Bonita Lavelle/EPR/R8/USEPA/US
09/07/2006 05:16 PM

To gerry@HH-LLP.net
cc
bcc
Subject electronic file of ambient air SAP

Hi Gerry

Here are 2 electronic versions of the draft "Sampling and Analysis Plan for Outdoor Ambient Air Monitoring at the Libby Asbestos Site" - one is in WORD so you can insert the comments from the LATAG and the other is a pdf version with all figures and tables. Hope this is useful. We look forward to your comments and really appreciate you sharing your thoughts so far!

Sincerely,

Bonnie Lavelle
Remedial Project Manager

EPA Region 8
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Denver, CO 80202

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Ambient Air SAP_Draft Final_ rev 2.doc


Draft_Final QAPP.pdf

LATAG

LIBBY AREA TECHNICAL ASSISTANCE GROUP, INC.

LATAG
P.O. Box 53
Libby, MT 59923
406-293-5535

September 15, 2006

Bonnie Lavelle
Remedial Project Manager
US EPA, 8EPR-SR
999 18th Street, Suite 200
Denver, CO 80202-2466

Dear Ms. Lavelle and Libby NPL Site Team:

Thank you for the opportunity to allow the Libby Area Technical Assistance Group (LATAG) to review the *Draft Final Sampling and Analysis Plan for Outdoor Ambient Air Monitoring at the Libby Asbestos Site, Libby, Montana,* dated Sep. 5, 2006, and prepared for EPA R8 by US DOT, CDM, and SRC.

We appreciate receiving the technical presentation and having discussions on this draft SAP that was provided by Mr. Paul Peronard and Dr. Aubrey Miller at our LATAG meeting on Sep 12. These interactions between EPA R8 staff and the LATAG members are valuable for promoting two-way understanding of concerns and rationales for important technical projects that are proposed to help assess risks at the Libby NPL site. The LATAG is also grateful that R8 hosts technical "pre-meetings" the week before our LATAG meetings, where detailed discussions of risk approaches and results can occur between our TA (Technical Advisor) and R8's Technical Team and Libby Remedial Team.

This SAP was thoroughly reviewed by our Technical Advisor, Dr. Gerry Henningsen, who incorporated any additional comments from other LATAG members into the attached reviews. Topics of major concern are attached, and minor edits or concerns are annotated as "mark-ups" in the Word document that you provided to help expedite and clarify our critical reviews. These technical comments are forwarded to your EPA office with the approval of the Executive Board of the LATAG.

Thank you for your cooperation in providing us with an electronic copy of this draft document that has helped to expedited and clarify our technical review.

Sincerely,

Gayla Benefield, Chair, LATAG

Major General Comments on the draft SAP for Outdoor Ambient Air Monitoring at Libby

1. Soundness of conceptual approaches appears weak and uncertain, which may reduce the quality and usability of the data and results
   a. Uncertainty exists in the risk-based concentration (RBC) due to a lack of CSF and RfC benchmarks for LA (Libby Amphibole) asbestos; the SAP uses chrysotile-driven values from EPA's IRIS (integrated risk information system) database of 0.23 "unit cancer risk" per fiber/ml, based upon PCM "structures" that are >0.4 um diameter and >5um long, and this translates to $1x10^{-4}$ cancer risk at 0.0004 f/ml or $1x10^{-5}$ cancer risk at the SAP's target analytical detection limit of 0.00004 f/ml adjusted as PCM structures with diameters >0.4 um and lengths >5um (uncertain quantitation limit) – but all this is still based on CHYSOTILE, and the identical approach would most likely be used by EPA if they were assessing exposures and risks for a site that only has chrysotile contamination, thus this approach is weak and flawed from the start.
   b. Reasonable estimates of LA asbestos potency range from about 10 to about 1000 fold more potent than chrysotile, probably due to tremolite asbestos content; while the EPA unit risk value has some contribution from amphiboles, it appears to be driven by mostly chrysotile studies and results, and therefore likely underestimates LA risks; if it turns out later that these estimates of greater potency are accurate, then the RBC and analytical methods must be correspondingly reduced by the difference in potency
   c. Use of $1x10^{-5}$ for the cancer risk endpoint in the draft SAP, instead of the usual unit risk endpoint at $1x10^{-4}$ provides some extra relative reduction in uncertainty of estimated RBC endpoint for LA, but the lowered analytical concentrations needed to quantitatively evaluate results in respect to undefined RBCs are therefore uncertain in their ability to quantitate the results or to confidently interpret the non-detect values.
2. objectives and goals are vague or weakly stated
   a. the premise of this SAP for its scientific logic is unconvincing, while political or other non-technical objectives and goals may be the primary impetus for this SAP
   b. pre-mature, rejected earlier ambient air report, R8 scientists said it was so bad that it would be buried and forgotten, but Max D proudly hailed in his June memo to LATAG
   c. general common-sense questions like, "what is your RBC (Risk-Based Concentration as # fibers / cm3) that you are using for this SAP?" cannot be accurately defined
      - What science is your RBC based upon? Is it any good or is it a wild guess?
      - How certain or uncertain is the science behind RBCs? i.e., what are the ranges of possible errors in risk?
      - Shouldn't you first know your toxicology to derive a solid RBC?
      - What is the upper end of the RANGE of RISK estimated by ND (non-detect) concentrations? Our TA had estimated an extra 1 in 100 cancer risk at the old ~DL (Detection Limit) or about 1 in 1000 upper bound for the new DL of 0.00004?!?
      - If LA asbestos is much more potent than chrysotile, for which these analytical methods were developed, then why not wait and at least TRY to have your EPA or contract lab chemists lower the DLs???

- What would it hurt EPA to re-prioritize their efforts towards getting the more critically needed "relative toxicity" screening study done in 6-9 months (estimated by some experts) and simultaneously task your chemists to explore options to lower and automate methods?
- Why can't counting of fibers be automated as are many similar particulates, using instrumented microscopes and software that is faster, accurate and cheaper overall?

- Given the flawed earlier ambient air study and report with essentially the SAME methods to collect fibers and to count them, isn't EPA taking excessive risks of possible failure by repeating the same findings – except for samples being taken from more wide-spread areas and over more seasons, and "planning to get ~ 10x lower detection limits?
  - If so, why not wait and improve EPA's chances to SUCCEED, by doing a quick tox screening study to better understand relative potency of LA, which directly corresponds to how much lower the analytical methods must push down the DLs to help interpret data in terms of EPA's risk-based health criteria? Please explain your pros and cons for pushing ahead now prematurely with the same inadequate tools and knowledge, vs getting those essential tox data and refining methods as needed for the relative toxicity; then EPA could confidently proceed with reasonable assurance of success, since you would know your toxic target and could have improved methods, which would allow you to better interpret the data and put them into realistic science perspectives.
  - If you are in fact, more or less proceeding with the same substandard methods and large uncertainties that plagued the earlier ambient air study and report, then we strongly suggest that EPA halt this effort immediately and wait until the higher priority tox studies and refinement of analyses are ready to use in such an air study; else it appears that EPA will waste more time and money by disappointing more residents with possibly very weak or relatively uninformative data.

Gerry M. Henningsen, DVM, PhD; DABT/DABVT
Technical Advisor, Libby Area Technical Assistance Group

Toxicologist and Senior Partner
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640 Yankee Lane 8A, Evansville, IN 47715-8185

"Dr. Gerry Henningsen"
<gerry@HH-LLP.net>

09/18/2006 05:32 AM

Please respond to gerry@HH-LLP.net

To: Bonita Lavelle/EPR/R8/USEPA/US@EPA, Paul Peronard/EPR/R8/USEPA/US@EPA, Jim Luey/EPR/R8/USEPA/US@EPA, Aubrey

cc: 'gaylab' <gaylab@libby.org>, 'Helen Andries' <helenandries@montanasky.net>, 'Brad Black' <brad@libbyasbestos.org>, montmac@libby.org,

bcc:

Subject: Markup Word File - RE: electronic file of ambient air SAP

Dear Bonnie:

Thanks again for agreeing to let me as TA and the LATAG to have electronic version of the SAP for submitting comments, edits, and suggestions to you. We hope the marked-up Word document lets you see where and why suggestions were offered, in the context of the document. As you likely know, Gayla sent the official set of major comments from the LATAG to you on Friday.

I thought that this SAP has the foundations for good use, but it was missing some critical details and justifications, almost as if it had been rushed to print without sufficient editing and reviewing by peers. I inserted questions about certain topics that were unclear, so that you can see how I perceived the material when reading the SAP. I also suggested alternative text and refined approaches that may improve understanding or complete overlooked areas. With some revisions by R8 to clarify meanings and to complete critical sections, I think this SAP should work up to your full expectations and needs.

Note, there were no signature blocks for EPA staff besides yours, Bonnie, and I think that your R8 scientists should also review and sign off on SAPs for approving technical matter in their fields of expertise. I suggested that Mary sign as a chemist for review of analytical methods, and that Aubrey or Wendy sign to attest to their review of toxicological and risk assessment topics. Besides the summary comments sent from Gayla last Friday, a couple other topics came to mind (as I got the Word file ready to return to you at R8) that you might find useful or may wish to discuss with your team and/or contractors.

1. The premise is made that LA in air samples is currently being released from soil samples in and around town, but that theory has not been tested or proven, as far as I know - especially at the Libby site. Therefore, I suggested that you might plan to collect a few scaled-back co-located composited surficial-soil samples in adjacent areas next to air monitoring stations, mostly where you find detectable LA but also at a few stations where you are not finding LA fibers. You could then have some purposeful sampling designed (usable biased data) that could either help to support, refute, or be inconclusive about the soil to outdoor air relationships for LA asbestos. I also think you would be better served to include a few comparative locales with samples from near roads, that the SAP currently argues is too dusty and may give atypical (higher) results; if the LA fiber counts are affected by traffic, then that's reality and it should be measured to some extent to get a reasonable idea of the relative degree that disturbance may have on airborne LA levels near traffic.

2. I was not comfortable with the conflicting approaches discussed in the text for evaluating and using the 0.45 um pore filters vs the 0.8 um pore filters. The initial 2-week comparison seemed to be a good idea, but later text seemed to state that the 0.8 um pore filters would be used anyway, especially since the past air samples used that

size. I am not totally convinced yet that East Helena is a suitable reference site, since the geological features are probably dissimilar as compared to Eureka or Kalispel and Yak vs Libby's; geological similarity, without known asbestos content, is usually the requirement for selecting good reference sites. I think you should either use a city nearby or else show us that Helena is similar enough to Libby to qualify it as a better site for background than are nearer communities (it may or may not matter, but it's your risk of possible loss of or discounting of the Helena site as an appropriate reference area for Libby).

3. Quite a lot of essential DQO information was missing from the SAP, for which I provided examples of information for you to consider including; e.g., definition of asbestos "structures", conversion factors planned for use in changing TEM data (mass or counts?) into corresponding PCM counts, and allowances for omitted particles that are outside structure sizes. The CSM was not mentioned, nor were various land-use scenarios (residential, commercial, etc.) or future uses. As stated in the LATAG review, I thought the objectives that we discussed with R8 and risk decisions were vague or missing.

4. There are still some troubling scientific contentions in this SAP that I do not think I or your scientists could defend.

a. Too much emphasis and undue credibility is given to the Dec 2005 report on ambient air with the June 2006 cover letter. I thought it was unacceptably biased, made too many unsubstantiated and subjective claims and assumptions, and had substandard data and used misguided analytical approaches that would mislead readers. I had recommended rejecting it to the LATAG, but we were told last June that this report would not be used and so R8 did not need to bother with any comments from the LATAG; however, this flawed document was used and even touted as if it had high quality science with unambiguous results and sound interpretations. Not!

b. There is little or no discussion of the status and uncertainties of the non-existent toxicity values for LA asbestos, wherein tremolite is the amphibole component that seems to drives risks. Tremolite has been tested to be much more potent than chrysotile, and Libby's clinical data appear to support this potency (severity, shorter onset, non-cancer disease, etc.). We all know that chrysotile is the main asbestos used to derive EPA's 1986 CSF and unit risk values, even though some studies with mixed amphiboles were considered in the derivations. The SAP uses EPA's chrysotile-based toxicity values, but the SAP has no discussion about the uncertainties for use or the CSF as a surrogate for LA, nor is there mention of the absence of relative toxicity data for LA asbestos. This uncertainty of the toxicity of LA must be presented in the SAP and not ignored. EPA can proceed to use the old EPA chrysotile-driven CSF values, since EPA has nothing better to use yet; however, EPA must be completely open about the large uncertainties, and acknowledge that risks are being quantified without knowing the site-specific toxicity of LA. This perspective is missing in the SAP, and uninformed readers will again be mislead into thinking that EPA knows the relative toxicity of LA asbestos. There is also too much inference about non-cancer risks, for which EPA has no RfC for LA or for chrysotile asbestos, while IRIS posted a completion date of 2008 for issuing the non-cancer RfC endpoint.

c. Since EPA has no confident toxicity values for LA, and EPA will have no more than a single exposure pathway assessed by this SAP, I do not see how R8 staff can begin to think there is enough scientific information to quantitative risk (given the lack of data and large uncertainties). Even with the best designed SAP, and this one should be fairly good after revisions, you cannot invent quantitative estimates of risks from qualitative data and other uncertain inputs. This SAP and its results, even with the highest quality, will only produce data that are suitable for risk-screening purposes. From such screening-level data, you should be able to tell:

i. if LA in air exceeds ER time-critical action-levels, denoting a need for more public health protection, or

ii. if LA levels are between the lower EPA chrysotile risk estimates and the higher ER action levels, to decide to screen-in and keep this exposure pathway for inclusion in the BLRA, or

iii. if LA levels are below EPA chrysotile risk estimates, then the ambient air exposure pathway may be insignificant at those locales that will be measured by this SAP

If EPA or your contractors try to model risks (from the limited SAP data) as quantitative estimates, you need to include ALL the variabilities and errors for exposure and toxicity into a full uncertainty analysis, which should clearly show how qualitative these risk estimates really are.

That covers most of my suggestions for you. I attached the mark-up Word file, a pdf file of the Word markups, and a pdf list of all the comments from the Word document. You should be able to quickly go through the Word review function to accept, reject, or modify the comments in your file. Thanks again for sharing the draft digital SAP with the LATAG and me. We hope you find this process useful, to help you review our comments more quickly and clearly. Have a good day, and call if you have questions.

Gerry

Gerry M. Henningsen, DVM, PhD; DABT/DABVT
Toxicologist and Senior Partner

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-----Original Message-----
From: Lavelle.Bonita@epamail.epa.gov [mailto:Lavelle.Bonita@epamail.epa.gov]
Sent: Wednesday, September 13, 2006 6:17 PM
To: gerry@HH-LLP.net
Subject: RE: electronic file of ambient air SAP

Hi Gerry

hey, I just wanted to make sure you knew I didn't intend to attach any "conditions" to sending you the electronic version of the ambient air SAP. You all have a right to request that version and as a public agency, I don't want to attach any conditions on you receiving it. Just wanted to find a way that I could avoid getting completely overwhelmed with competing comments on multiple electronic files. Hope you all understand....

I think we found a good solution to the potential problem I was worried about. I hope it's not too much work for you to consolidate comments.
If you find it is, let's talk about other solutions.

looking forward to the LATAG's comments.
take care!
Bonnie

"Dr. Gerry Henningsen" <gerry@HH-LLP.net>
09/08/2006 07:51 AM
Please respond to gerry@HH-LLP.net

To: Bonita Lavelle/EPR/R8/USEPA/US@EPA
cc:
Subject: RE: electronic file of ambient air SAP

Thanks, Bonnie!

This will be helpful, and hopefully more useful and easier for R8, as well as helping the LATAG to better understand technical comments. I relayed your conditions for digital reviews, and the due date of 15 Sep. We appreciate the frank discussions on these topics, as they help the LATAG better understand and to have more confidence in the R8 processes that are foreign to their thinking. Have a great day.

Gerry

Gerry M. Henningsen, DVM, PhD; DABT/DABVT Toxicologist and Senior Partner H & H Scientific Services, LLP 640 Yankee Lane 8A, Evansville, IN 47715-8185 phones: 812-459-3518 (cell) 812-303-5578
(local) email: gerry@HH-LLP.net

-----Original Message-----
From: Lavelle.Bonita@epamail.epa.gov
[mailto:Lavelle.Bonita@epamail.epa.gov]

Sent: Thursday, September 07, 2006 6:16 PM
To: gerry@HH-LLP.net
Subject: electronic file of ambient air SAP

Hi Gerry

Here are 2 electronic versions of the draft "Sampling and Analysis Plan for Outdoor Ambient Air Monitoring at the Libby Asbestos Site" - one is in WORD so you can insert the comments from the LATAG and the other is a
pdf version with all figures and tables. Hope this is useful. We
look forward to your comments and really appreciate you sharing your thoughts so far!

Sincerely,

Bonnie Lavelle
Remedial Project Manager

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(See attached file: Ambient Air SAP_Draft Final_ rev 2.doc) (See attached file: Draft_Final QAPP.pdf)

Gerry-MarkUps Ambient Air SAP_Draft Final_ rev 2.pdf

Gerry-MarkUp LIST Ambient Air SAP_Draft Final_ rev 2.pdf

Gerry-MarkUps Ambient Air SAP_Draft Final_ rev 2.doc

Draft Final
Sampling and Analysis Plan
for Outdoor Ambient Air Monitoring
of Libby Amphibole Asbestos Fibers~~at the~~
at the Libby Asbestos Site
Libby, Montana

Comment [GH1]: Mark-up comments and suggestions are provided for R8 to consider as possible improvements of the accuracy and completeness of technical information and for improved clarity by readers who may not be familiar with the regulatory and technical terminology; suggestions are intended as constructive criticism to help strengthen the SAP for EPA R8

September 5, 2006

Contract No. DTRS57-05-D-30109
Task Order No. 00006

Prepared for:

U.S. Environmental Protection Agency
Region VIII
999 18th Street, Suite 500
Denver, Colorado 80202-2466

Prepared by:

U.S. Department of Transportation
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John A. Volpe Center National Transportation Systems Center
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and

CDM Federal Programs Corporation
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with technical support from:

Syracuse Research Corporation
999 18th Street, Suite 1975

Denver, CO 80202

Draft Final
Sampling and Analysis Plan for
Outdoor Ambient Air Monitoring at the
Libby Asbestos Site
Libby, Montana

September 5, 2006

Contract No. DTRS57-05-D-30109
Task Order No. 00006

Approved by:_____ Date: _____
George Siple, QEP
CDM Technical Reviewer

Approved by:_____ Date: _____
Kim Zilis
CDM Quality Assurance Reviewer

Approved by:_____ Date:_____
Steve Losier
Volpe Center Project Manager

Approved by:_____ Date:
_____
Dr. Aubrey Miller or Wendy O'Brien
EPA Risk Assessor

Approved by:_____ Date:
_____
Mary Goldade
EPA Chemist

Approved by:_____ Date: _____
Bonita Lavelle

Comment [GH2]: Approval signatures should include R8 scientists with applicable expertise for the document, to show their review and acceptance of the science

EPA Remedial Project Manager

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Contents

Acronyms

ARD	Asbestos Related Disease
BNSF	Burlington Northern Santa Fe (railroad)
CAR	Corrective Action Request
CDM	Camp Dresser McGee (Federal Programs Corporation)
COC	chain-of-custody
CSF	Cancer Slope Factor
CSM	Conceptual Site Model
DQOs	data quality objectives
EDD	electronic data deliverable
EPA	U.S. Environmental Protection Agency
FSDS	field sample data sheet
FSP	field sampling plan
HASP	health and safety plan
HQ	hazard quotient
ISO	International Organization for Standardization
KDC	Kootenai Development Corporation
LA	Libby amphibole (asbestos)
MCE	mixed cellulose ester
MET	meteorological
NOAA	National Oceanic and Atmospheric Administration
NPL	National Priorities List
OU	operable unit
PCM	phase contrast microscopy
~~PLN~~	~~Poisson~~lognormal
PM	project manager
PPE	personal protective equipment
QA	quality assurance
QAPP	quality assurance project plan
QC	quality control
RBC	Risk-Based Concentration
RfC	~~cumulative~~ reference concentration
RPM	remedial project manager
SAP	sampling and analysis plan
~~S~~s/cc	structures per cubic centimeter
SOP	standard operating procedure
TEM	transmission electron microscopy
TWF	time weighted fraction
UCL	upper confidence limit
um	micrometer
Volpe Center	John A. Volpe National Transportation Systems Center
%	percent

Comment [GH3]: data were weak and likely driven by ND values set to 0 in prior AA report, so Poisson distribution is not a given, but data could result in a lognormal or other distributional shape

Section 1
Introduction

Comment [GH4]: Could use better context about:
1-"why" the study is needed
2-how the CSM supports SAP
3-uncertainties with approach

This document ~~serves as~~describes the sampling and analysis plan (SAP) for an outdoor ambient air monitoring program ~~to be initiated~~scheduled to begin in September 2006 as part of the ongoing remedial investigation for the Libby Asbestos Site Operable Unit (OU) 4. This SAP outlines the ~~sampling~~sample ~~and~~collections and analytical ~~sis~~ methods to be conducted by CDM Federal Programs Corporation (CDM) personnel ~~during the~~for representative collection of outdoor ambient air samples during the next year within the Libby Valley.

This SAP contains the QA/QC elements required for both a field sampling plan (FSP) and quality assurance project plan (QAPP). This SAP has been developed in accordance with the *Environmental Protection Agency (EPA) Requirements for Quality Assurance Project Plans* (EPA 2001) and the *Guidance on Systematic Planning Using the Data Quality Objectives Process – EPA QA/G4* (EPA 2006a).

The purpose of this SAP is to describe the sampling objectives, locations, numbers, durations, measurement methods, ~~and~~ data quality objectives (DQOs) and other details for the outdoor ambient air sampling program. The SAP is organized as follows:

Section 1 - Introduction
Section 2 – Site Background
Section 3 – Data Quality Objectives
Section 4 – Sampling Program, Rationale, and Locations
Section 5 – Laboratory Analysis and Requirements
Section 6 – Assessment and Oversight
Section 7 – Data Validation and Usability
Section 8 - References

Appendices

Appendix A – Standard Operating Procedures (SOPs)
Appendix B – Stationary Air Field Sample Data Sheet (FSDS)
Appendix C – Outdoor Ambient Air Sampling Program Daily Impact/Observation Memorandum
Appendix D – Libby Asbestos Project Record of Deviation Form
Appendix E – Example of Equipment Shelter

1.1 Objectives

This section defines scientific objectives of the ambient air monitoring ~~program~~studies and the intended use of the data.

As determined by previous screening-level investigations conducted at the Site, Libby

[illegible]

amphibole (LA) ~~is~~asbestos fibers are present in multiple environmental media in Libby including: indoor air, outdoor ambient air, indoor dust, vermiculite insulation, ~~and~~ soils, and possibly other environmental media (water, vegetation, etc.). As a result, residents of Libby ~~may~~are ~~be~~ exposed to LA at concentrations yet to be characterized, and these exposures may pose ~~a~~excess risks of cancer (especially mesotheliomas) and/or adverse non-cancer effects (asbestos related disease – ARD). One exposure pathway that is of major potential concern to EPA is inhalation of LA in outdoor ambient air, and the relative contribution of this pathway to cumulative exposures must be characterized for quantitative use in a baseline risk assessment (BLRA). A conceptual site model (CSM) has been developed by EPA R8 (2006c) that helps to provide a framework and basis for designing sample collections that will evaluate the major complete exposure pathways for LA asbestos fibers in the air at Libby. Earlier screening of ambient air was performed to support EPA Emergency Response time-critical removal actions, but these results were not representative and had differing analytical methods with varying sensitivities that were being refined (2006b).

Comment [GH5]: Not a question of if or maybe

There are ~~two~~several objectives ~~of the program~~for this SAP:

1. ~~–~~The first objective is ~~to~~ to ensure ambient air concentrations of LA asbestos are not so high that they may pose acute toxic risks or may exceed R8 Emergency Response action-levels for estimated high risks of chronic toxicity; thus, the urgent need exists to expedite studies of this exposure pathway to ensure that public health at Libby is presently safeguarded against immediate severe risks. ~~collect data of sufficient representativeness and quality to estimate the human health risks associated with inhalation of LA in outdoor ambient air in and around the town of Libby. Estimates of human health risks require the characterization of the long-term average concentrations of LA.~~

2. The second objective is to characterize the nature and extent of LA asbestos contamination, spatially and temporally at OU4, including the determination of whether significant differences of patterns of LA asbestos are evident. ~~collect data to characterize the spatial patterns and temporal trends of LA occurrence in outdoor ambient air within the study area at the Libby Superfund Site.~~

~~1.~~3. The third objective is to characterize exposures from outdoor ambient air concentrations of LA asbestos, and use the results to begin to estimate the contributions to potential risks from ambient air – based upon highly uncertain estimates of toxic benchmarks for LA asbestos fibers and structures

Comment [GH6]: These objectives seem premature since EPA does not have RBCs with sufficient quality to begin to estimate health risks with any confidence, and these objectives differ from the main verbal objectives explained during discussions with R8 managers and scientists; so I have tried to re-phrase those objectives to better match our technical understanding of them; again the original first objective is not feasible to achieve since no confident toxicity estimates for LA asbestos (tremolite) exists yet, and so any such attempt at risk estimates would be a highly uncertain and subjective modeling exercise with little reality

The specific ~~activities~~procedures detailed in this SAP will be used to scientifically plan ~~implement~~ and conduct a monitoring program of LA asbestos in ~~for~~ outdoor ambient air in the Libby Valley. Sampling will be conducted at ~~a~~ specified frequenc~~y~~ies from multiple locations chosen to provide representative spatial and temporal coverage of study area.

1.2 Project Schedule and Deliverables

Sampling is ~~expected~~planned to begin in September 2006 and will continue on a regular schedule until the EPA risk assessment and management teams determine that the amount of data collected is sufficient to support final decision-making goals for this exposure pathway as depicted in the CSM (2006c). Interim data reports summarizing all outdoor ambient air data collected to date will be generated no less than once every two months in order to keep project managers informed as to the data quality, results, and interim findings.

Section 2
Site Background

This section describes the site location, history, and information regarding collections and measurements of previous outdoor ambient air data during Emergency Response time-critical removal actions.

2.1 Site Location

The Libby Asbestos Site, OU4, is located within Sections 3 and 10, Township 30 North (T30N), Range 31 West (R31W) of the Libby Quadrangle in Lincoln County, Montana (Figure 2-1). The Site includes homes and other businesses, which may have become contaminated with LA asbestos fibers as a result of the historic vermiculite mining and processing conducted in and around the City of Libby.

2.2 Site History

Since 1999, the US EPA R8 Superfund Program has ~~been~~ conducted~~ing sampling and~~ cleanup activities with limited sampling to begin to address exposures and estimated risks in the more highly contaminated areas in the Libby Valley. The initial EPA investigation was mainly undertaken ~~initiated~~ in response to news media articles, which detailed extensive asbestos-related health problems in ~~the Libby population~~Libby residents. While at first the situation was thought to be limited to ~~these~~workers and their families with direct or indirect occupational exposures, it soon became clear that LA contamination was widespread and there were multiple exposure pathways and many persons with no link to mining-related activities who were affected with ARD (asbestos related diseases).

The site was listed on the Superfund National Priorities List (NPL) in February 2002.

For long-term management purposes, the Libby Asbestos Site has been divided into seven OUs:

- OU1. ~~The former Export Plant~~This area is defined geographically by the property boundary of the parcel of land that included the former Export Plant.

Comment [GH7]: Redundant

- OU2. The exact geographic area of OU2 has not yet been defined, but includes areas impacted by contamination released at and from activities associated with the former Screening Plant. These areas include the former Screening Plant, the Flyway property, the Highway 37 Right of Way adjacent to the former Screening Plant and Rainy Creek Road, the Wise property, and the Kootenai Development Corporation (KDC) Bluffs. The KDC Bluffs area is located directly across the Kootenai River from the former Screening Plant.

- OU3. The mine ~~OU~~and associated areas ~~-~~includes a) the former vermiculite mine, owned and operated by the WR Grace Company, located northeast of Libby; b) the ~~geographic~~ areas (including ponds) surrounding the former vermiculite mine that haves been impacted by releases of LA from the mine, including Rainy Creek and the Kootenai River; and c) releases of LA asbestos along Rainy Creek Road. The exact geographic area of OU3 has not yet been

defined but will be based primarily upon the extent of LA contamination associated with releases from the former vermiculite mine.

- OU4. ~~OU4~~This ~~is defined as~~area contains residential, commercial, industrial, and public properties, including schools and parks in or near Libby. OU4 also includes highway corridors. The exact geographic area of OU4 has not yet been defined but will be based primarily upon the extent of LA contamination associated with releases from local point and non-point sources.

- OU5. The former Stimson Lumber Mill is defined geographically by the parcel of land that included the former Stimson Mill.

- OU6. The rail yard owned and operated by the Burlington Northern and Santa Fe Railroad (BNSF) is defined geographically by the BNSF property boundaries and extent of LA asbestos contamination associated with the rail yard. OU6 includes railroad transportation corridors. The exact geographic area of OU6 has not yet been defined but will be based primarily upon the extent of LA contamination associated with releases from local point and non-point sources.

- OU7. ~~The Troy~~This area ~~OU~~ includes all residential, commercial, and public properties within the town of Troy. The exact geographic area of OU6 has not yet been defined but will be based primarily upon the extent of LA contamination associated with releases from local point and non-point sources.

EPA is conducting ~~a~~ baseline human health risk assessments (BLRA) for all OU~~4~~s. The baseline human health risk assessment will be incorporated into the remedial investigation and feasibility study for the OUs~~4~~. This outdoor ambient air monitoring plan is focused on collecting data according to major complete exposure pathways in the CSM (see figure?), to support the human health baseline risk assessment for OU4. Although outdoor ambient air in OU4 may be impacted by any activity that causes LA to be released from a source, it is currently believed that the main source of LA in outdoor ambient air in the vicinity of Libby is release from physical disturbances of contaminated soil in and around the community. This is because contaminated soils generally occur as non-point sources in multiple locations in and around Libby, and because major waste piles and other obvious sources of LA ~~are believed to~~ have been recently removed by EPA~~from Libby~~. The remaining contaminated soils in Libby can serve as a continuous source of LA release into the air. Releases of LA from soil into outdoor ambient air may be due either to disturbances from wind blowing over the soil, or from a variety of other disturbances of ~~the~~ soil by human activities ~~which occur randomly~~.

Comment [GH8]: Don't know if the activities are random or not.

2.3 Summary of Prior Outdoor Ambient Air Monitoring in Libby

Beginning around 2000 and continuing through the year 2002 , EPA collected outdoor ambient air samples at a number of locations around Libby in order to gain an initial

understanding of the ~~levels~~range~~-~~ of LA contamination typically observed in outdoor air. Locations where samples were collected included:

- Fitness Center at the City Hall Building (952 East Spruce Street)
- McGrade Elementary School (899 Farm to Market Road)
- Plummer Elementary School (247 Indian Head Road)
- Rainy Creek Road (various locations from intersection with Highway 37 to turnouts along the road to the mine summit)
- Lincoln County Courthouse Annex (418 Mineral Avenue)
- Lincoln County Landfill
- Station FA-1 (on the northwestern boundary of the River Runs Through It subdivision)
- Stimson Lumber Property

These samples were collected to support various removal actions and to evaluate different sample~~ing programs~~ collection procedures and analytical methods. Details regarding sample collection procedures during ER time-critical removal actions and analytical methods are described in the Summary of Asbestos Levels in Ambient Air in Libby, Montana report prepared by EPA (EPA 2006b). At some locations, air samples were collected over the entire three-year period from 2000 to 2002. ~~At other locations, air samples were collected for less than three years.~~ Because of the evolving analytical methods with changing MDLs, due to the screening nature of those samples for limited purposes, the results of those varied studies are limited in their ability to provide representative and quantitative results with acceptable confidence.

In addition, samples of outdoor ambient air were collected at 27 properties in Libby where EPA clean-up activities were scheduled. ~~These samples were collected before clean-up began, and~~ The measurements were intended to help determine if the clean-up activities caused a measurable release to outdoor ambient air. These samples were collected and analyzed in accordance with the Draft Final Response Action Work Plan (CDM 2003a). The duration of sampling at these individual properties was limited to one to two days.

~~The results of these samples were evaluated in the Summary of Asbestos Levels in Ambient Air in Libby, Montana report (EPA 2006b).~~ The conclusions of this report were as follows:

Comment [GH9]: Redundant information stated above

- The presence of LA fibers was identified in some outdoor ambient air samples collected around the Libby community, but analytical methods and their sensitivity (MDLs) changed repeatedly over the 3 years of sample collections.
- Sources of the LA fibers found in outdoor ambient air in Libby are not known with certainty, but it seems likely that windborne transport of fibers present in soils and dust around the community ~~is~~ may be a~~n~~ ~~important component~~important contributor to exposures.
- ~~Concentrations levels did~~ not appear to be substantially different at different locations within the main residential-commercial section of Libby~~, but may be higher closer to the mine~~.
- Current data are too limited to determine if any time trend towards ~~reduced~~changed ~~-~~ levels in outdoor ambient air is occurring as a result of on-going

Comment [GH10]: Data do not support this, it is speculation.

Comment [GH11]: NO! You have no basis to only study one pre-conceived direction of change, instead of either way.

EPA clean-up activities~~, but collection of additional current and future outdoor ambient air data will help answer this question.~~

The conclusions of the initial ambient air summary report are limited by the following:

- Data presented in the report are incomplete because of lack of seasonal and geographic represe*n*tation~~, over time~~, and there are ~~an~~ insufficient ~~number of~~ data points with ~~at~~ inadequate levels of analytical sensitivity.
- The preliminary analyses ~~presented~~ assumed that "non-detect" values weare equal to zero, rather than setting NDs at the MDL concentration or at ½ the MDL, as described in EPA RAGS Part A.. USEPA Region 8 is currently reviewing ~~this~~ approaches for analyzing "non-detect" results.
- The methodology for estimating risk ranges is preliminary and should be considered draft, and is subject to change for improving confidence of results.
- Evaluation of risk in the document is highly uncertain, has severely limited uses, only ~~to~~evaluates a single pathway and does not address cumulative exposure from multiple pathways at the Site.

EPA identified the need for further investigations of outdoor ambient air in Libby and its vicinity, specifically: collection of additional outdoor ambient air data; refinement of ~~the~~analytical ~~-~~ methodology, for improvements in estimating human health risk ranges and uncertainties for the Libby population; and consideration of other exposure pathways (see the CSM, 2006c) cumulative historic exposures in evaluating risk.

Comment [GH12]: Redundant

Comment [GH13]: This EPA report was reviewed by the TA earlier and found to have serious deficiencies and uncertainties that greatly limited its use and prevented any confident interpretation of the results, and supposedly the R8 technical team had similar opinions. This section and others should clearly point out *the problems with an* uncertain RBC, changing analytical methods with varying detection limits, and the other factors that effectively negate the ability to draw any defensible scientific conclusions about quantitative risk estimates from the early sampling that had other purposes with alternate designs. Both the strengths and limitations of the current SAP design and analytical approach need to be fully explained.

Comment [GH14]: The map in Fig 2 could use updating to include 1) the city of TROY, 2) the meaning of the green dashed rectangle around Libby, 3) location of the mine site, and 4) railroads; since these and other nearby areas were contaminated with LA asbestos. Why have the Eastern cities or Kalispel included, when Troy is omitted?

Section 3
Data Quality Objectives

The DQO ~~process, based on scientific methods, is~~process uses a series of scientific planning steps that are designed to ensure that the type, quantity, and quality of environmental data used in decision-making are appropriate for the intended purpose. EPA ~~has~~ issued guidelines to help ~~data~~ users of data (risk assessors and risk managers) develop site-specific DQOs (EPA 2006a). These guidelines were followed for the development of ~~the~~ DQOs presented in this section.

Comment [GH15]: Data is a noun and not usually used nor is as clearly comprehended as an adjective

The DQO process specifies project ~~decisions~~decisions that need to be made, specific data types needed, data collection requirements, analytical techniques, and the data quality required to support those decisions, ~~specific data types needed, data collection requirements, and analytical techniques necessary to generate the specified data quality~~. The process also helps ensures that the resources required to generate ~~the~~ usable (DURAS 1992) data are reasonably justified. The DQO process consists of seven steps~~;~~, and output from each step influences the choices that will be made later in the process. These steps include:

Comment [GH16]: Seems out or progressive order

Comment [GH17]: Thus the comment about the proper sequential order for readers to follow along

1. State the problem
2. Identify the decision to be made
3. Identify the inputs used to make the decision
4. Define the study boundaries
5. Develop a decision rule for use of the data
6. Specify tolerable limits on data variability and uncertainty that must be met to minimize decision errors
7. Optimize the design for data collection and analyses

Comment [GH18]: Else this reads as if a decision has already been made, which it has not

3.1 Step 1 – State the Problem

The purpose of this step is to describe the problem to be studied so that the focus of the investigation will be unambiguous.

Comment [GH19]: I don't read a clearly stated problem in this paragraph, so I suggested an acceptable problem statement as an example for you to consider specifying.

As determined by previous investigations conducted at the Site, LA asbestos is present in multiple environmental media in Libby including: indoor air, outdoor ambient air, indoor dust, vermiculite insulation, ~~and~~ soils, etc.. As a result, residents of Libby may be over-exposed to LA, and these exposures may pose a risk of cancer and/or non-cancer effects. One exposure pathway that is of ~~potential~~ major concern to EPA is inhalation of LA fibers in outdoor ambient air (see CSM, 2006c). However, as noted above (see Section 2.3), the current data set for LA concentrations in outdoor ambient air in Libby is not extensive or reliable enough to support risk assessment calculations for this exposure pathway with acceptable levels of confidence. This is

Comment [GH20]: There is no question that people are and have been exposed to LA; the LA is present in all media.

Comment [GH21]: Run-on sentence

because the data ~~may~~are ~~be fully~~ representative over geographic area and~~/or~~ time, ~~and because many of~~ the ~~data~~ analyses have ~~a~~ high MDLs (method detection limits) from ~~(~~poor~~)~~ analytical sensitivity, and the hazard posed by shorter fibers than the conventional structures is uncertain, as is the relative toxicity of LA asbestos. ~~which tend. to~~These limitations reduce accuracy and confidence in estimates of long-term average exposure levels, especially when most samples had ND (non-detectable) concentrations of LA asbestos using the initial analytical methods.

~~-~~The problem that this SAP is intended to help resolve involves the filling of data-gaps with results that: 1) representatively characterize LA concentrations over time (four seasons) and space (OU4) with more reliable data; 2) comprehensively measure peak and mean LA concentrations in sections of OU4 to help assess the adequacy of EPA Emergency Response removal actions in protecting public health from relatively high exposures (that may exceed time-critical action levels and warrant more immediate interventions); and 3) estimate approximate risk contributions to exposed people from the single exposure pathway of inhaled LA fibers in ambient air, per the CSM (2006c).

3.2 Step 2 – Identify the Decision to be Made

This step identifies what questions the investigation will attempt to resolve and what actions may result.

The decisions that EPA is seeking to make ~~is~~are:
1) whether the levels of LA in outdoor ambient air contribute to excessive exposures and ~~a~~associated high levels of estimated risk of cancer or non-cancer effects, based on interim toxicity benchmarks and RME exposure factors for this single pathway analyses;
2) determine if the results are able to identify significant differences in patterns or trends of LA concentrations over time and space in OU4; and
3) determine when and if sufficient data with adequate quality and sensitivity (based on MDLs compared to eventual RBCs) have been collected to reliably use in a quantitative baseline risk assessment.
~~either~~Qualitative or semi-quantative risks (i.e., high, medium, or low) can only be estimated at this time with these single exposure pathway results and with the uncertain interim-RBCs and present analytical sensitivity. These results can later be combined with additional site data to estimate cumulative exposures and total site risks ~~alone or~~ in combination with other exposure pathways, per the CSM (2006c). ~~that is within an a~~Acceptable ~~range of~~ risks will be calculated ~~usingnder a~~ reasonable maximum exposure factors and the ER removal-action concentration as a screening level risk endpoint.~~scenario~~. Actual quantitative risk calculations for cancer and non-cancer endpoints cannot be performed until EPA conducts or uses qualified toxicology studies to obtain a scientifically credible CSF and RfC for LA. Cumulative risks cannot be quantitated until EPA has sufficient site data on LA contamination for all major exposure pathways at Libby. The CSM for ambient air in OU4 is a good starting point for guiding sampling that begins to fill all major data-gaps. The current screening-level risk assessment will support EPA's decisions about whether additional clean-up actions (over and above those already occurring in Libby) are needed to reduce or eliminate other sources of LA contamination in Libby that contribute to outdoor ambient air exposures.

Comment [GH22]: EPA does not have any RfC yet, nor a CSF that is specific for LA – with tremolite as the suspected ultimate toxicant; therefore, EPA cannot estimate risks with any certainty without reliable site RBCs, and single pathway analyses may or may not drive *risks as the main contributor* of exposure to LA asbestos. This decision can NOT be made at this time for use in quantitative risk assessment.

Comment [GH23]: EPA cannot do more at this time than to roughly estimate risks in a screening-level approach, since that is all that defensible science will support without site-specific RBCs and with only a single pathway of site exposure data. Once EPA establishes a credible CSF and RfC for LA, and has collected multimedia exposure data, then quantitative risk assessments can be prepared. To try to do more than a screening-level risk analysis at this time will be fool-hardy due to lack of essential site data.

3.3 Step 3 – Identify the Inputs to the Decision

The purpose of this step is to identify the environmental data that need to be obtained and the measurements that need to be taken to resolve the decision statements.

The key environmental data required to estimate cancer and non-cancer risks from exposure to outdoor ambient air ~~are~~must be reliable, risk-based, and representative (over space and time) ~~data on the~~ for determining long-term average concentration of LA in outdoor ambient air within ~~an~~ exposure units at the Site. These data, if reliable and of adequate quality, may then be analyzed using appropriate statistical methods to determine if there are important spatial patterns (i.e., significant differences between sub-areas) or important time trends in the data (e.g., significant differences between ~~summer and winter~~seasons, a ~~decreasing~~ changing time trend as cleanup activities continue, etc.). Based on these ~~analyses~~evaluations, the data may then be grouped into appropriate geographical and temporal ~~data~~ subsets, from which long-term average LA concentration and RME exposure values may be calculated. The long-term average value for a specified area and time frame is probably the key determinant of ~~the~~ cancer and non-cancer risk to residents and workers exposed in that area and time.

Comment [GH24]: You cannot pre-suppose that there may only be changes in one downward direction! Your valid stats must evaluated trends as a two-tailed test for changes in either direction, else you bias the results.

Comment [GH25]: This is subjective speculation, since you do not yet know the exposure scenarios that can produce these diseases; the clinical data for patients exposed to LA seem to indicate that some patients have shorter durations of intermittent exposures to LA that also seems to produce ARD with a shorter onset than the usual chronic durations of exposures associated with chrysotile asbestos. The point is that you should not make such claims without site data or applicable studies to back up such assumptions.

Due to the lack of a site-specific toxicity benchmark, even though the uncertain EPA 1986 CSF was used as the ER trigger level for screening time-critical risks (derived predominantly from chrysotile asbestos exposures in workers), it is premature at this time to try to quantitate risks from LA asbestos, since results would be too uncertain. Some scientific inputs that will be used for screening risks now and for quantitating risks later, include:

1) the ER action-level criteria as a toxicity screening benchmark, using EPA's inhalation unit risk level of 0.23 per (f/ml), whereby 0.0004 f/ml equates to an excess cancer risk of $1x10^{-4}$ which is at the high end of EPA's cleanup goal; IRIS advises not to use this unit risk value for asbestos if fiber counts in air exceed 0.04 f/ml, since the cancer slopes were not predictable above this concentration.

2) concentrations of LA asbestos fibers that are counted by TEM at sizes >0.15um diameter and >0.5um length with at least 3:1 aspect ratios (length to width),

3) analytical MDLs and MQLs (method detection and quantitation limits) for setting and interpreting non-detect (ND) values, with the target MDL set at 0.00004 f/ml.;

4) appropriate surrogate values for ND results that are not equal to zero (e.g., substitute the ND value with the MDL or half the MQL, etc.);

5) conversion factors for adjusting TEM fiber counts to PCM "structures", typically structures are defined as fibers >0.4um diameter and >5.0 um in length with a 3:1 aspect ratio, but are so highly uncertain that EPA does not recommended a conversion factor; TEM mass conversions to PCM structures are also very uncertain; these conversions are sometimes applied because the CSF unit risk value is based on PCM structure counts from the historic occupational studies. IRIS reports that TEM methods can count 2 to 4 times more fibers than PCM which are >5um and <0.4um; thus short narrow fibers that are counted by TEM are overlooked by PCM.

6. An option that should be considered on a scaled-back basis for this SAP, is to collect a few co-located composited surface-soil samples in the vicinities of the air sampling sites, where LA asbestos fibers are detected in air. The results from this subset of soil samples could be used to test the stated hypothesis that the primary source of LA in air is the adjacent surface soil that is also contaminated with LA. This sampling would be purposeful and biased to determine if elevated LA contamination in soil is the main contributor to co-located LA in air. This sampling could be considered to start next spring after many results should be reported for the air samples, and when much of the snow has disappeared. Correlations or other associations between air and soil samples could help strengthen the knowledge and justification for either ignoring or pursuing additional soil sources of LA asbestos.

7. Location data coordinates will need to be reported and used as inputs for the analyses, and GPS is suggested as a preferred method to accurately locate samples for the long term (after property addresses and structures and owners may change).

In this regard, it is important to recognize that there are several alternative strategies for specifying the concentration of asbestos in air and in using those data to estimate exposure and screening-level risks. At present, final decisions have not been made regarding which approach(es) will be used, so it is important that the data obtained provide full details on the particle size (length, width, mineral type) of all asbestos ~~structures~~fibers observed, so that these data can be used to compute the appropriate concentration values for use in whatever alternative risk models may be selected for eventual quantitative use at the Site.

Comment [GH26]: This term is not defined by the authors, and should be specified; I suggested some dimensions for structures that the EPA IRIS database uses.

3.4 Step 4 – Define the Boundaries of the Study

This step specifies the spatial and temporal boundaries of this investigation.

Spatial Bounds

The study will focus on collection of data from OU4 that are representative of the main residential-commercial area of the Libby Valley. This area is indicated in Figure 3-1. This area is selected as the focus of this program because this is where the majority of area residents and workers live and work. Levels of LA in outdoor ambient air in other parts of OU4 as well as locations associated with other Operable Units ~~(e.g., the mine, Rainy Creek Road, Stimson Lumber, the former Screening Plant, Export Plant and other former processing facilities, the community of Troy, etc.)~~ will be investigated under separate sampling designs, as necessary (e.g., the mine, Rainy Creek Road, Stimson Lumber, the former Screening Plant, Export Plant and other former processing facilities, the community of Troy, etc.).

Based on the limited and uncertain data available to date, and based on the subjective evaluation of the preliminary results, no clear differences weare apparent in average LA concentrations in different sub-locations in the main residential commercial area of Libby (identified as Zones 1, 2 and 3 in the ambient air summary report [EPA 2006b]). Therefore, it may be appropriate to consider the main residential-commercial area of the Libby Valley as one ~~exposure~~operational sub-unit and to calculate the long-term average concentration of LA in outdoor ambient air by combining all the data. However, if the new data reveal important spatial variations in long-term

Comment [GH27]: NO! An exposure unit is not defined and used this way, but is meant to contain the spatial area where human receptors obtain the majority of their exposures for specified scenarios of land-use activities. This needs to be replaced with a correct term.

average (as estimated by repeated samples collected over about one year) outdoor ambient air levels, then it may be appropriate to subdivide the main area of Libby into two or more sub-areas, each of which would be considered separate ~~exposure~~ contamination source units and would be evaluated separately for this pathway. Individual property exposure units will be evaluated according to the human receptors' land-use, such as commercial, light-industrial, residential, recreational, school activities, etc.

In addition to samples in the main residential-commercial parts of Libby, samples will also be collected at several stations that are well removed from the Libby Site such that impact from past or present releases of LA are not expected to be of concern. Data from these reference stations will be used to assess the ~~magnitude~~ relative differences between background LA asbestos and that of Site-related releases to outdoor ambient air.

Comment [GH28]: The background samples are NOT useful for assessing "magnitudes" of site releases!

Temporal Bounds

The program ~~will~~is planned to begin in September 2006 and continue for about one year. ~~At present, t~~The exact duration of the monitoring program ~~cannot be stated with certainty~~is flexible, since the frequency and duration and magnitude of temporal variability (by day, by season, by year) is not yet known. Further, the ~~magnitude of any~~ effect of on-going clean-up actions on outdoor ambient air levels is not known. ~~However, in order to ensure that temporal variability on the scale of days and months is adequately captured in the data set, it is expected that the program will endure a minimum of 1 year.~~ If it is determined that there is a need to capture additional data to improve the temporal representativeness of the data set and/or to collect data that will allow ~~an~~better assessment of long-term trends that may be resulting from on-going cleanup activities, then ~~it is expected that the~~ ~~program~~sample collections and analyses ~~c~~would be extended ~~for several additional years~~. These decisions will be made by the risk assessors and risk managers, once the data collected from the initial year are collected, and after consultation with EPA's scientific support team at the Site.

Comment [GH29]: More than simple magnitude of LA will be evaluated and reported.

Comment [GH30]: Does not add much

Comment [GH31]: There is overuse of "program", which is used in a vague and loose manner throughout the SAP; recommend it be replaced with more descriptive text.

3.5 Step 5 – Develop Decision Rules

The purpose of this step is to describe the method that EPA will use to make final risk management decisions from the data and reported results.

At present, risk management decision rules for the Site have not yet been defined. Because outdoor ambient air is only one of several exposure pathways that will be evaluated as part of the baseline human health risk assessment, it is expected that the decision rule for outdoor ambient air will ~~take the form that the residual~~evaluate residual cancer and non-cancer risk using ~~associated with the~~ reasonable maximum exposure ~~scenario~~factors and future more-confident RBCs for multiple land-use scenarios and for both current and future receptors. ~~contributed by this pathway may not exceed some specified level (either an absolute level or alternatively, some proportion of the total risk).~~

Based on the stated objectives in this SAP, the risk management goals are understood to be 1) ensure that protection is being afforded residents from excessive exposures so

that estimated risks do not exceed the ER time-critical action criteria; 2) collect and analyze air data for LA to better understand the nature and extent of contamination, for discerning if meaningful patterns of differing exposures occur over time and space; and 3) attempt to collect sufficient reliable data that has the quality to be used eventually in a quantitative BLRA.

In the absence of a quantitative decision rule, it is ~~tentatively~~ assumed for the purposes of planning the air monitoring program for LA, that if estimated risks associated with inhalation of outdoor ambient air under reasonable maximum exposure conditions approach or exceed a cancer risk level of 1E-05 (~~one in 100,000~~) or a non-cancer Hazard Quotient (HQ) of 0.1, however, this non-cancer RBC has not yet been developed by EPA) then the sampled area and exposure scenario would screen into the quantitative BLRA. Concentrations and exposures that exceed these levels of tentative risk would be evaluated further in respect to time-critical removal actions; whereas, concentrations and exposure scenarios that estimated risks to be below these screening criteria could be ruled out (not major contributors to LA exposures). ~~outdoor ambient air pathway may be an important contributor to the total cumulative risk and that, in this case, the sampling program should have a high ability to detect and reliably quantify the ambient air levels. This assumption is for planning purposes and should not be interpreted as a risk management decision since~~ fFinal risk management decisions will consider ~~the~~ cumulative risks of exposure to multiple exposure pathways. ~~This assumption is used only to support initial efforts to plan the monitoring program.~~

3.6 Step 6 – Specify Tolerable Limits on Decision Errors

The tolerable limits on decision errors, used to establish performance goals for the data collection design, are specified in this step.

In making risk management decisions with calculated estimates of exposure and risk, two types of decision errors are possible:

Comment [GH32]: This is premature until a defensible site RBC is obtained.

- A Type I (false negative) decision error would occur if a risk manager decides that exposure to outdoor ambient air is not of significant health concern, when in fact it is of concern – per EPA risk criteria.

- A Type II (false positive) decision error would occur if a risk manager decides that exposure to outdoor ambient air is above a level of concern, when in fact it is not.

EPA is most concerned about guarding against the occurrence of Type I errors, since an error of this type may leave humans mistakenly exposed to unacceptable levels of LA in outdoor ambient air. For this reason, it is anticipated that exposure assessment for this pathway will be based on RME exposure factors, current and future land-use scenarios, exposure unit areas that approximate residential yards or business property and the best estimate and the 95% upper confidence limit (UCL) of the long-term average concentration of LA in the area being evaluated. Use of the UCL to estimate exposure and risk helps account for limitations in the data, and provides a margin of safety in the risk calculations, ensuring that risk estimates are unlikely to be too low.

EPA is also concerned with the probability of making Type II (false positive) decision errors. Although this type of decision error does not result in unacceptable human exposure, it may result in unnecessary expenditure of resources. For the purposes of this effort, the strategy adopted for controlling Type II errors is to ensure that if the risk estimate based on the 95% UCL is above EPA's level of concern for this pathway, then the UCL is not larger than 3-times the best estimate of the mean. If the 95% UCL is at or above the range that is of potential concern, and the UCL is greater than 3 times the best estimate of the mean, then more data may be needed.

Comment [GH33]: The concept seems OK but the approach seems arbitrary. What is the basis for selecting a UCL 3x > mean? Scientists conventionally use the CV, coefficient of variation to try to visualize the variation of their data, which is defined as the SD / mean. CVs are usually preferred to be 50% or less and usually not more than 100%, or else your data may be too variable and uncertain. Please explain and justify the use of this 3x UCL approach, or else use the standard CV calculations.

Aspects of data quality that affect the decision errors above, include usability factors (DURAS 1992) such as:

- if and how well PARCC criteria are met in the study (precision, accuracy, representativeness, completeness, consistency)
- applying and carrying through, as appropriate, variability and uncertainty in ALL inputs besides the 95% UCL of average concentrations described above; ranges of values can be carried through, e.g., CTE (central tendency exposures) to RME range, or distributional analyses (Monte Carlo, etc.) can be used to help better describe the variability and uncertainties of the data and results
- other input factors that certainly have variability and uncertainties include: RBCs, MDLs, control samples, individual exposure factors, etc.
- a thorough uncertainty analysis should always be performed on data and results to inform risk managers of the confidence or lack thereof they should have in the results of a study

3.7 Step 7 - Optimize the Design for Obtaining Data

This step identifies a resource-effective data collection design for generating data that are expected to satisfy the DQOs.

Comment [GH34]: NO! This report was not finalized, and the data and results were so weak and variable, and the approach too subjective, that no distribution can be scientifically defined for those uncertain screening-level data that were designed and collected for ER purposes.

Estimating the Number of Samples Required

The method used to compute the UCL of a set of outdoor ambient air samples depends on the statistical properties and quality of the data set. ~~Analysis of data available to date indicates that the variability between outdoor ambient air samples may be approximated by a mixed Poisson lognormal (PLN) distribution~~. Statistical procedures are available to estimate the parameters of the underlying lognormal distribution (Haas et al. 1999), and these fitted parameters may be used to compute the UCL of the mean (s/cc by PCM, or TEM mass or counts per fractional size?) using the approach for lognormal data sets described in EPA 1992a. Based on this approach, the ratio of the UCL to the mean of a data set (an indication of the statistical variability and uncertainty in the data) is given by

Comment [GH35]: The measured endpoint is not specified, but left undefined. This SAP should have the numerical data defined for eventual analyses. Perhaps both types of columns can be reported and evaluated for certain purposes.

Comment [GH36]: Not just uncertainty, since the UCL is calculated from the SD, which describes variability.

$$\frac{UCL}{Mean} = \exp[\sigma H / \sqrt{(n-1)}]$$

where:

σ = log standard deviation of the measured values
H = statistic described in USEPA (1992)
n = number of samples

Based on available data for air samples from the study area (Zones 1-3 identified in the ambient air summary report (EPA 2006b)), a rough approximation for σ for outdoor ambient air samples from the main part of Libby is 1.9. Figure 3-2 (center line) illustrates the ratio of the UCL to the mean as a function of n for an assumed σ of 1.9. As seen, the ratio (a measure of uncertainty) approaches a value of about 2 as the number of samples approaches about 80-100, and continues to decline slowly as the number of samples increases. Note that a similar pattern ~~in~~is observed for values of σ that are somewhat smaller (lower line) or somewhat higher (upper line).

Based on this analysis, it is expected that if a total of about 80-100 samples per exposure area were collected, and if the value of sigma is in the range of 1.5-2.3 (GSD = 5-10), the uncertainty and variability in exposure estimates would be limited to less than a factor of 3 (based only upon uncertainty analyses for a single input - the concentration term)., ~~and that~~ In this example, collection of additional samples would result in only minor decreases in uncertainty.

Comment [GH37]: Who are you kidding?!? This is an exercise in futility, because the many other inputs for the exposure estimate all have as much or more uncertainty and variability as the C-Term. This approach is incomplete and therefore is misleading! This section needs rewriting to omit the strong references to the former air report and to minimize the implied confidence about the C-Term value in respect to overall uncertainty an d variability of all the data used.

If resulting data (collected over a year's time) support the assumption that the entire study area represents a single exposure unit, then ample data will be collected – well beyond the required 80-100 data points per exposure unit area. However, for study planning purposes, such an assumption cannot be made *a priori*. If it is assumed that it may be necessary to divide the study area into 2-3 sub-areas to account for spatial variability, there will likely be 2-3 stations per sub-area, and this will yield 72-108 samples per year per sub-area, which will still be enough to support the study DQOs on their own. The data will be periodically evaluated to determine whether the sample variability supports application of one or more exposure units within the study area and/or whether continuance of the outdoor ambient air monitoring is warranted.

Comment [GH38]: This conclusion assumes that only the C-Term has any meaningful variability and uncertainty that would affect the results and the sample size needed to statistically compare and describe the data. This should also be caveated to fit the actual science better.

Estimating the Required Analytical Sensitivity

As noted above, for the purposes of this planning document, it is assumed that the analytical sensitivity must be sufficient to ensure reliable detection and quantification if estimated risks from outdoor ambient air approach or exceed a cancer risk of 1E-05 (~~1 in 100,000~~based exactly upon the current EPA IRIS chrysotile-driven asbestos CSF) or a non-cancer HQ of 0.1 (for which no RfC value exists, and it is not due to be released until 2008, per EPA). The concentrations tentatively associated with these screening risk levels may be estimated as described below.

For cancer, a simplified equation for computing the risk associated with some specified concentration is:

$$Risk = C \cdot TWF \cdot UR$$

where:

Risk = risk of lung cancer or mesothelioma from the exposure being evaluated
C = long-term average concentration of asbestos (structures per cubic centimeter [s/cc])
TWF = time weighting factor (percent of full time that exposure occurs)
UR = unit risk for lifetime exposure

The target analytical sensitivity, assuming that a confident RBC is available (which it is not), is then computed by rearranging the equation as follows:

$$\text{Target Analytical Sensitivity} \leq 1E\text{-}05 / (TWF \cdot UR)$$

For planning purposes, it is conservatively assumed that the TWF is 1.0. This corresponds to exposure to outdoor ambient air that occurs 24 hrs/day for a lifetime (EPA default = 30 years, but actual exposures are likely to be lower than this for most people). Based on EPA's currently recommended risk model (IRIS 2006), the unit risk factor for lifetime exposure is 0.23. Thus, the level of concern for LA in air would be about:

$$\text{Target Analytical Sensitivity} \leq 1E\text{-}05 / 0.23 = 0.00004 \text{ PCM s/cc (defined as ?)}$$

Comment [GH39]: This needs to be specified in the SAP; and the conversion units and justifications for TEM data to PCM data needs to be explained and the uncertainty included into calculations of any screening risk estimates.

where:

PCM = phase contrast microscopy

For non-cancer effects, the basic risk equation to be used after EPA publishes an RfC for asbestos (ideally for LA) is:

$$HQ = C \cdot (ET/24 \cdot EF/365 \cdot ED) / RfC$$

where:

HQ = hazard quotient (dimensionless)
C = long-term average concentration of asbestos in air (f/cc)
ET = exposure time (hrs/day)
EF = exposure frequency (days/yr)
ED = exposure duration (yrs)
RfC = Cumulative Reference concentration (f/cc-yrs)

However, at present, no RfC has been established for evaluating non-cancer effects from inhalation of LA, so it is not yet possible to compute an analogous level of concern for this endpoint. In the absence of data, it is tentatively assumed that the target analytical sensitivity that is adequate for evaluating cancer risk will also be sufficient for evaluating non-cancer risks. This assumption will be re-visited when an RfC is developed.

Thus, the target analytical sensitivity for outdoor ambient air samples should be ≤ 0.00004 UNITS? cc^{-1}.

Comment [GH40]: No units are specified, but they must be given; they are presumed to be s (structures) for determining PCM equivalent risk estimates. Please specify.

Analytical results for samples that report ND (non-detect) will need to specify the actual achieved MDL and MQL for the sample, along with all relevant QC data and results to help interpret the ND value for use in risk estimates. EPA RAGS Part A (1989) recommends using ½ the MQL or MDL, or some other rational approach, but zero is not recommended as a surrogate value due to the uncertainty involved in regards to estimated risks to exposed persons.

Refinements to the Design as Data are Collected

In accord with EPA's DQO process, it is expected that the outdoor ambient air monitoring program described in this document may be modified periodically as data are obtained. For example, if data suggest that the variability in concentrations over time is low, then EPA may decrease the number of samples collected over a specified period of time. Alternatively, if data suggest that the variability in concentrations over geographic areas is higher than expected, then additional sampling stations may be added to better characterize the spatial variability. Similarly, the target analytical sensitivity may be either increased or decreased, depending on the detection frequency and mean values observed in initial samples results, and on the RfC value when it becomes available.

Section 4
Sampling Program

This section provides brief summaries of SOPs and additional site-specific detail that may not be discussed in the SOPs. The site-specific procedure will be followed during this investigation. For additional information, field personnel will refer to the SOPs included in Appendix A. The site health and safety plan (HASP) should be consulted to determine health and safety protocols for performing site work. The SOPs and site-specific procedures included in Appendix A are listed below (CDM 2005b):

- Sample Custody (SOP 1-2)
- Packaging and Shipping of Environmental Samples (SOP 2-1)
- Guide to Handling of Investigation-Derived Waste (Modified SOP 2-2)
- Field Logbook Content and Control (SOP 4-1)
- Photographic Documentation of Field Activities (Modified SOP 4-2)
- Control of Measurement and Test Equipment (SOP 5-1)
- Asbestos Air Sampling at Libby (CDM-SOP-LIBBY-AIR) – this SOP is currently under development

Comment [GH41]: Why not use GPS to record coordinates in a more permanent manner?

The following sections are a summary of field activities that will be performed in accordance with this SAP by CDM during the outdoor ambient air sampling investigation.

4.1 Pre-Sampling Activities

Prior to beginning field activities, a field planning meeting will be conducted and an inventory of supplies will be performed to determine procurements needs. The following sections discuss these pre-sampling activities.

4.1.1 Field Planning Meeting

Prior to beginning field activities, a field planning meeting will be conducted by the CDM project manager (PM) and attended by the field staff and a member of the CDM quality assurance (QA) staff as well as EPA support scientists who were instrumental in study design development. The EPA Remedial Project Manger will be notified of the date and time of the meeting. The agenda will be reviewed and approved by the QA staff and the health and safety officer prior to the meeting. The meeting will briefly discuss and clarify:

- Objectives and scope of the fieldwork
- Equipment and training needs

- Field operating procedures, schedules of events, and individual assignments
- Required quality control (QC) measures
- Health and safety requirements
- Documents governing fieldwork that must be on site
- Any changes in the field plan documents

Comment [GH42]: Examples? Not described yet, and so some idea of QC would help.

A written agenda, reviewed by the CDM QA staff, will be distributed and an attendance list signed. Copies of these documents are maintained in the project files, in the CDM Denver office. Additional meetings will be held when the documents governing fieldwork require it or when the scope of the assignment changes significantly.

The field team personnel will perform the following activities before and during field activities, as applicable:

- Review and understand this SAP and HASP
- Ensure that all sample analyses are scheduled through the laboratory
- Obtain required sample containers and other supplies
- Obtain and check field sampling equipment
- Obtain personal protective equipment (PPE)

Comment [GH43]: State if certified and pre-qualified.

4.1.2 Inventory and Procurement of Equipment and Supplies

The following equipment will be required for sampling activities, and any required equipment not already contained in the field equipment supply inventory will be procured prior to initiation of sampling activities:

- Field logbooks
- Indelible ink pens
- Digital camera
- Sample media: 0.8 micrometer (um) pore size, 25-millimeter diameter mixed cellulose ester (MCE) filter cassettes.
- Sample paperwork and sample tags/labels
- Custody seals
- Zipper-top baggies
- Air sampling equipment as described in CDM-SOP-LIBBY-AIR
- PPE as required by the HASP

4.1.3 Community Coordination

Prior to the implementation of the sampling events described in this SAP, the owner of each property where sampling is proposed will be contacted to determine his/her desire to participate in this investigation. The property owner will be advised of the study's duration (at least a year and perhaps longer) and will be informed of the importance of obtaining samples consistently over that extended time period. Access agreements will be obtained as required. A community involvement coordinator will contact each resident to describe the program and the potential impact to the resident (e.g., sample technicians visiting the property at regular intervals, the expected duration of the program). Each residential or commercial property participating in this investigation will be reimbursed for power used from their service to run sampling equipment.

Comment [GH44]: No rate of repeated sampling has yet been defined, so some summary of what is meant by "consistent over a year" would help readers.

4.2 Field Documentation

Field documentation to be generated during this sampling study includes the following: logbooks, FSDSs, photographs, and sample custody documentation. The following sections describe the types of documentation as well as how field documents will be corrected if errors occur and the process for documenting deviations from field procedures prescribed in this SAP.

4.2.1 Field Logbooks and Records

Field logbooks will be maintained in accordance with CDM SOP 4-1, Field Logbook Content and Control (Appendix A). This log is an accounting of activities at the Site and will note problems or deviations from the governing plans and observations relating to the sampling and analysis program. Field administrative staff will manage the logbooks and FSDS and will send original field logbooks, as they are completed, to the CDM project file repository in Denver, Colorado for document control. A copy of each logbook will be maintained in the CDM office in Libby, Montana.

Detailed sampling notes will be recorded for each sample on an FSDS (Appendix B). Field administrative staff will manage the FSDSs and will send copies to the CDM project file repository in Denver, Colorado for document control and a copy to the John A. Volpe National Transportation Systems Center (Volpe Center) for data entry required in the project database. Original FSDSs will be maintained in the CDM office in Libby, Montana.

For each day that outdoor ambient air samples are collected in association with this SAP, a Daily Impact/Observation Memorandum will be completed. An example of this memorandum is included in Appendix C. The purpose of this memorandum is to capture, in an easy to access format, any actions or issues that could affect the results or viability of an outdoor ambient air sample.

4.2.2 Photographic Documentation

Photographic documentation will be recorded for each sampling location (at first collection event) and at any place the field sampling personnel determine necessary with a digital camera in accordance with CDM SOP 4-2, Photographic Documentation of Field Activities (Appendix A) with the following site-specific modifications.

Section 5.2.2, General Guidelines for Still Photography - A slate is not required for each new roll of film. The information for the slate will be recorded in the field logbook (e.g., direction of the photograph, surrounding landmarks, etc.). All team members, as stated in the logbook, will be photographers and witnesses at the locations. Slates are not required for close-up photographs, and instead the required information can be listed in the digital photograph file name. File names will be in the format: last name of property owner_address_AAS_date, where:
AAS = Ambient Air Sampling
Date = MM/DD/YY

Comment [GH45]: Don't you use digital images and video? Why not if you don't? Later it seems as if you can, but here it does not look like you use anything but rolls of film.

A color strip is not required for close-up or feature photographs.

Section 5.2.4, Photographic Documentation - The name of the laboratory, time and date of drop-off, and receipt of film are not required to be recorded for this project.

Section 3.3.2, Archive Procedures - Digital photographs will be archived on the CDM Libby Server (secure) with nightly backup. These files will be archived until project closeout, at which point project management will determine a long-term electronic file storage system.

4.2.3 Sample Labeling and Identification

Samples will be labeled with index identification numbers supplied by field administrative staff, and will be signed out by the sampling teams (i.e., controlled). One sample label will be placed on the sampling cassette. The sample identification number will also be written on the outside of the plastic bag used to hold the sampling cassette during transport.

Sample index identification numbers will identify the samples collected during the outdoor ambient air study by having the following format:

AA-LYYO-#####

Where: AA = Ambient air
= a sequential five digit number

Comment [GH46]: Would it help you and labs or readers to have some additional code on your labels, such as shown as an example for the site (L = Libby, T= Troy, etc.) and YY = year where 06 = 2006, and O = OU, such as 4 for Libby SAP? If you do not provide this summary ID info, then readers will need a data-dictionary to decode the samples numbers. You do not discuss any decode plans here.

4.2.4 Field Sample Custody and Documentation

Sample custody and documentation will follow the requirements specified in CDM SOP 1-2, Sample Custody (Appendix A). All samples and sampling paper work will be relinquished to the sample coordinator at the end of each day. Field administrative staff will be responsible for management of all field forms.

4.2.5 Corrections to and Deviations from Documentation

Logbook modification requirements are described in CDM SOP 4-1, Field Logbook Content and Control (Appendix A). For the logbooks, a single strikeout initial and date is required for documentation changes. The correct information should be entered in close proximity to the erroneous entry. These procedures will also be followed for the correction of any field form. All deviations from the guiding documents will be recorded on the Daily Impact/Observation Memorandum

(Appendix C) and the Libby Asbestos Project Record of Modification Form (Appendix D). Any major deviations will be documented according to the CDM quality management plan (CDM 2005a).

4.3 Outdoor Ambient Air Sampling

The following sections describe the process of selection of outdoor ambient air sampling locations, the procedures for sample collection, and requirements for collection and submission of QA/QC samples.

4.3.1 Selection of Outdoor Ambient Air Sampling Locations

Outdoor ambient air sampling will be conducted at 14 specified locations in the main residential/commercial area of Libby (Figure 4-1). This number of stations was selected so that, if the data indicate that it is necessary to divide the study area into 2-3 sub-areas to account for spatial variability in long-term averages, there will likely be at least 3-5 stations present in each sub-area, which will help ensure that the data set for each sub-area remains spatially representative.

The locations of these 14 stations were selected using a stratified random approach, in which the study area was divided into 14 grids, and 1 location was selected within each grid. The specific location within each grid was chosen on a random basis by selecting locations that have available electricity and could be accessed year-round. This is important to help ensure that the stations will provide adequate spatial coverage of the study area.

In addition to the 14 outdoor ambient air sampling locations shown in Figure 4-1, two background samples will be collected; in Eureka and Helena, Montana. Eureka was chosen because it is a location known to have buildings with vermiculite attic insulation. The Eureka sample will be collected at the city office building located at 108 Dewey Avenue. The Helena sample will be collected at the local CDM office located at 50 West 14th Street.

Comment [GH47]: Is Helena preferable to Kalispel or Yak, etc. as a reference area? Conceptually, the reference areas should be from similar geological formations, to get the best background samples for LA asbestos fibers

Meteorological (MET) data station data will be downloaded daily from the internet for the following weather stations as reported hourly by the National Oceanic and Atmospheric Administration (NOAA):

- Libby Fire Cache (NOAA station identification = LBBM8)
- Eureka (NOAA station identification = EURM8)
- Helena Regional Airport (NOAA station identification = KHLN)

Although not considered necessary for the calculation of risk data, MET data may be used to understand temporal patterns of results and sample representativeness.

4.3.2 Sampling Protocol

Outdoor ambient air samples will be collected and equipment calibrated in accordance with CDM-SOP-LIBBY-AIR which is based on EPA SOP #2015 (Appendix A) for asbestos air sampling. In brief, outdoor ambient air sampling pumps will be placed on the east or west side of buildings approximately 15 feet away from outer walls to reduce building interference with wind patterns and allow the samples to be exposed to the dominant northwest to southeast air patterns in the valley. Sample

Comment [GH48]: I fail to understand your explanation for keeping units out of prevailing wind, if you are going to allow the units on the west side but not the south side, for the reason that winds blow NW to SE. Why have the west side designated but not the south side?? Please explain or correct.

locations will be chosen so that particulates generated by automobile traffic on dirt and gravel roads will be minimized.

Equipment shelters, such as those shown in Appendix E, will be used to house the sampling pumps. The use of these shelters will protect the sampling equipment from adverse weather conditions that would otherwise interfere with the collection of year-round samples.

4.3.2.1 Collection Interval and Flow Rates

In order to help ensure that target analytical sensitivities can be achieved, the target volume of air to be collected for each sample will be 14,000 liters. To help ensure that samples capture temporal variability, each sample will be collected over a 5 day (120 hour) interval. Thus, the target flow rate is approximately 2 liters per minute. At each station, a second sample will be collected with a lower flow rate (1.5 liters per minute) over the same period of time. This sample is intended to serve as a backup for use if the sample collected at the higher flow rate is overloaded. This, the low flow sample will initially be archived, and will not be analyzed unless the primary sample is overloaded.

As samples are initially collected during this program and analyzed, these flow rates and sample times may be adjusted to ensure the sample filter has proper loading for the required analytical analysis and sensitivity goals.

4.3.2.2 Sampling Schedule

At each station, sampling will occur on a regular 10 day schedule. This will result in the collection of 36 samples per year per station. Table 4-1 shows an example of the staggered schedule for the first month of the investigation. The schedule presented in Table 4-1 is only intended to provide an example for execution, and specific start dates for each sample location may be adjusted.

Sample collection will begin over a 3 to 4 hour period on a predetermined day of the week. During the first two weeks of sampling collection, every sample will be checked every 3 to 4 hours, after that each sample cassette will be checked every 6 to 8 hours for visible loading. If visible loading is observed on a filter, or if decreased flow is noted due to filter plugging, the collection of that sample will be concluded, duration of collection will be noted, and the sample submitted for analysis. Samples will not be submitted on more than one cassette if visible loading is observed, instead the analysis of the sample will be modified (more grid openings counted) to ensure the appropriate analytical sensitivity is reached.

The sampling schedule and techniques for the Helena station will be the same as for stations in Libby. Due to the remote location of the Eureka sampling location (70 miles north-northeast of Libby), samples from this station will be collected over a 32-hour period once a week. To account for the shorter sampling period, somewhat higher flow rates (8 and 5 liters/minute) will be used so that the sample volumes collected will be similar to the volumes that will be collected in Libby.

Sampling may be suspended if adverse weather conditions exist (e.g., precipitation that could interfere with sample viability and/or equipment function, hazardous

Comment [GH49]: This seems to defeat part of your stated purpose for sampling to ensure no areas exceed higher levels of LA concentrations *that may pose public health* threats!! Why not add a couple purposeful sampling stations near suspected areas of more disturbance to learn if they perhaps are or are not more hazardous??? I think you should reconsider this position and include some of these sites, which would NOT be included in your overall database, but would be separated like your reference samples and lab PE samples. If you don't do the sampling now, questions will arise later about how safe or dangerous this situation is, so why not include a few samples (not all 36)?

Comment [GH50]: I do not understand why you could not replace a plugged filter with a new one during the 5-day sample period, and then combine the filter results. Please justify, and tell why you stop when full, rather than insert a new filter.

Comment [GH51]: The *number of total annual* samples per station seems more than necessary at 36 each or 9 per quarter (3 per month, 5 days each); I would suspect that similar results and conclusions should be able to be determined with 24 samples per year per station. Why this number? It seems adequate but may be excessive, since related text claimed 50-100 per subunit may be adequate to discern different spatial patterns. Are you trying to attain that number of 50-100 samples each quarter and for ea ... [1]

Comment [GH52]: Why check them so often? Are they that unreliable or need that much attention? Unless essential, it would seem like checking each 4-6 hr s at first and then backing off to 8-12 would be more reasonable, unless there is some good reason.

Comment [GH53]: Why so much shorter? Could not *these be run for half the time* (60 hours) at twice the rate? That is still about a 3+ day window, an d it seems more comparable to the Libby samples.

winter road conditions). If this occurs, the EPA RPM will be notified immediately. It is suspected that due to the use of the equipment shelters (Appendix E) sampling will only be affected by extreme weather.

4.3.2.3 Filter Type

Samples will be collected using 25-millimeter diameter, 0.8 um pore size MCE filter cassettes. The choice of 0.8 um pore size is based on the fact that most air samples collected in Libby to date have used this pore size.

In order to investigate whether the choice of pore size is an important determinant of observed concentrations, samples using 0.45 um pore size filters will also be collected during the first two sampling events at the following six stations:

- 1915 Kootenai River Road
- 1593 Highway 2 W
- 60 Port Blvd
- Cabinet View Golf Course
- 475 Fish Hatchery Road
- 122 Evans Rd

These locations were selected to represent 2 sampling stations from the north end of the study area, the middle of the study area, and the south end of the study area.

This will result in collection of 12 sets of paired samples (same place, same time, different pore size) that will be compared using appropriate statistical tests determine if there is any meaningful difference in samples results as a function of pore size.

Comment [GH54]: This section does not discuss the initial testing with the filters with smaller pore sizes of 0.45 um, as indicated earlier would be initially used unless particulates plugged the pores. How do you know that the smaller size fractions will not pass through the 0.8 um filters??? Any studies of filter efficiency for retaining various fiber sizes of interest here? How much small fiber LA gets through each filter?

Comment [GH55]: If so, are you going to convert to only using 0.45 um as implied? Or might you split up locations and use half 0.8 and half 0.45?

4.3.2.4 Sample Height

All samples will be collected from the height of an adult's breathing zone, approximately 6 feet above ground level by using lengths of tygon tubing that reach from the sampling pump positioned near the ground to a sampling stand designed to hold the sampling media at desired heights.

In order to investigate whether levels may tend to be higher at a child's breathing height (3 feet) than at an adult's breathing height (6 feet), samples will be collected at both 3 feet and 6 feet above ground level during the first two sampling rounds at the following 6 sampling locations:

- 1915 Kootenai River Road
- 1593 Highway 2 W
- 60 Port Blvd
- Cabinet View Golf Course
- 475 Fish Hatchery Road
- 122 Evans Rd

These locations were selected to represent 2 sampling stations from the north end of the study area, the middle of the study area, and the south end of the study area.

This will result in the collection of 12 pairs of filters (same location, same time,

different heights) that will be compared using appropriate statistical methods to determine if there are any meaningful differences between the heights, and this information will be used to determine whether continued sampling at both 3 feet and 6 feet is required.

Comment [GH56]: Will you anchor the units down to avoid weather and vandals? Will they be cordoned off with a small temp. fence?

4.3.2.5 Duration of the Sampling Schedule

As noted above, the full duration of the monitoring program can not be specified with certainty at this time, but it is expected that the program will last for at least 1 year, and may extend beyond that point. Assuming that 36 samples per year are collected from each of 14 stations in the Libby study area, this will result in the collection of a minimum of 504 additional outdoor ambient air samples. As noted above, this number is expected to provide a good characterization of both geo-spatial and temporal variability, even if it is necessary to divide the study area into 2-3 sub-locations.

4.3.3 Chain-of-Custody Requirements

Chain-of custody (COC) procedures will follow the requirements as stated in CDM SOP 1-2, Sample Custody with modification (Appendix A). The COC record is used as physical evidence of sample custody and control. This record system provides the means to identify, track, and monitor each individual sample from the point of collection through final data reporting. A complete COC record is required to accompany each shipment of samples.

At the end of each day, all samples will be relinquished to the sample coordinator by the sampling team following COC procedures. The sample coordinator will follow COC procedures to ensure proper sample custody between acceptance of the sample from the field teams to shipment to the laboratory.

Comment [GH57]: Have you done studies or have data on the amount of asbestos fiber that reaches the filter vs. gets adsorbed to the surfaces of tygon tubing or other internal surfaces? Do you know the percent mass and how it changes over time?

Also, do you have data on the efficiency of the filters in trapping most or all of the fibers, even small ones, at the various flow rates and for the differing pore sizes? If not, can you do any small investigations to see if this is a concern of any significance? For instance, can you prove that perhaps 10% of all small fibers adhere to pre-filter surfaces; or can you show that a substantial fraction does not pass through the filters? TEM *reportedly counts* fibers >0.15 um and lengths >0.5 um, which is smaller than 0.8 and about the size of the 0.45. I'd like to see some verification results to ensure you are capturing all the LA in the ambient air, and that the air sampling device is not interfering or failing with the measurements.

4.3.4 Sample Packaging and Shipping

Samples will be packaged and shipped in accordance with CDM SOP 2-1, Packaging and Shipping of Environmental Samples, with modification (Appendix A). A custody seal will be placed so that both ends of the sampling cassette are covered by the seal. If an overnight delivery service is used to ship the samples, the samples will be secured for shipment in a rigid container with sufficient packing material to prevent dislodging the collected fibers. Vermiculite, shredded paper, or expanded polystyrene cannot be used as packing material. Plastic bubble wrap is an example of an acceptable packing material.

4.4 Equipment Decontamination

Sampling will be completed with dedicated field equipment, and equipment decontamination will not be required for the activities described in this SAP.

4.5 Handling Investigation Derived Waste

Any disposable equipment or other investigation derived wastes will be handled in accordance with CDM SOP 2-2 with Site-specific modifications, Guide to Handling of Investigation-Derived Waste (Appendix A).

4.6 QA/QC Activities

This section describes the QA/QC activities that will be conducted to ensure samples collected during this effort are of sufficient quality to meet the project DQOs.

4.6.1 Calibration and Control of Sampling Equipment

Prior to the collection of samples, sampling pumps will be calibrated to the required flow rate by use of an adequately maintained secondary calibration standard according to CDM SOP 5-1, Control of Measurement and Test Equipment (Appendix A) and EPA SOP 2015 (Appendix A).

Comment [GH58]: Each use; i.e., 3 times / mo? Please specify

4.6.2 Collection of QA/QC Field Samples

Three types of QA/QC samples will be collected as part of this investigation: lot blanks, field blanks, and co-located samples.

Lot blanks - Before samples are collected, two cassette lot blanks from each filter lot of 100 cassettes will be randomly selected and submitted for analysis. The lot blanks will be analyzed for asbestos fibers by the same method as will be used for field sample analysis. The entire batch of cassettes will be rejected if any asbestos fiber is detected on the lot blanks.

Field blanks - One field blank will be collected each day and one analyzed per week for this sampling study, as described in field modification LFO-000064. If asbestos fibers are observed on a field blank, other field blanks collected during that week will be submitted for analysis to determine the potential impact on sample results. The field blanks will be analyzed for asbestos fibers by the same method as will be used for field sample analysis. The blanks will be collected at varying locations throughout the week (one collected at a different location on each day of the week).

Comment [GH59]: Could you briefly summarize how you will prepare and handle a field blank?

Co-located samples - Co-located samples are used to determine the variability of the measured parameter. Due to the nature of outdoor ambient air, these samples should not be used to assess measurement error (EPA 1992b). The co-located samples are only intended to measure the variability of the measured parameter. Co-located samples will be collected at a frequency of one per week. Field co-located samples will be collected beside a field sample and given a unique index identification number. Field co-located samples should be collected from varying locations throughout the study area. The sampler will assign the same location ID to the co-located sample as the field sample, and will record the identification number of the field sample on the FSDS in the comments section. Co-located samples will be sent for analysis by the same method as field samples.

Comment [GH60]: Please explain this statement, and how you will use the results. Will you determine RPDs, and then how will you use them? Please tell why these samples cannot be used to help assess error.

Section 5
Laboratory Analysis and Requirements

The laboratories used for all sample analysis will have participated in, and acceptably analyzed, the required parameters in the last two proficiency examinations from the National Institute of Standards and Technology/National Voluntary Laboratory Accreditation Program. The laboratory must also analyze performance evaluation samples when requested. These analyses must be performed before any samples are submitted to the laboratory to confirm the laboratory's capabilities and may be subsequently submitted at regular intervals. In addition, the laboratory must participate in the laboratory training program developed by the Libby laboratory team.

Comment [GH61]: PE samples are not defined;

5.1 Analytical Methods

The outdoor ambient air and QA/QC samples will be submitted to a subcontracted laboratory for analysis using the International Organization for Standardization (ISO) transmission electron microscopy (TEM) method 10312, also known as ISO 10312:1995(E) (CDM 2005c) with project specific modifications LB-000016, LB-000019, LB-000028, LB-000029, LB-000029a, LB-000030 (CDM 2003b). All asbestos structures (including not only Libby amphibole but all other asbestos types as well) having length greater than or equal to 0.5 um and an aspect ratio ≥ 3:1 will be recorded on the Libby site-specific laboratory data sheets and electronic deliverables.

Comment [GH62]: Please explain what all will be reported; e.g., counts, dimensions, mineralogy, mass of TEM fibers, structures? Definition of structures? Etc.

As stated in LB-000029 and LB-000029a, the frequency for laboratory-based QC samples for TEM analysis is:

Lab blank = 4%
Recount same = 1%
Recount different = 2.5%
Re-preparation = 1%
Verified analysis = 1%
Inter-laboratory = 0.5%

Comment [GH63]: the inter-lab QC rates for TEM is only 1 of 200, which seems quite low; conversions from TEM to PCM for risk estimation is not explained; why can't sequential filters be collected over the 5 days, if they become loaded earlier? Is this because it will be another costly sample, rather than summing the counts for 5 days of air monitoring? The target MDL of 0.00004 s/cc is equated to the predominantly chrysotile asbestos CSF, and TEM conversions of all asbestos fibers are not provided, and they have limitations.

Due to concerns related to the efficiency of sampling pumps over the required sampling time, 0.8 um filters will be used instead of the traditional 0.45 um called for when collecting samples for TEM analysis. In addition, the use of 0.8 um filters willmay help reduce loading concerns typically encountered when collecting samples of long duration and high volume. ~~Historical ambient air samples at the site were also collected on 0.8 um filters; by using these filters for this sampling program, data comparability will be improved.~~

Comment [GH64]: This sentence contradicts the text that said a comparison would decide the pore size, whereas *here it appears as if the* outcome is predetermined! Do the test to show the most relevant filter pore size!

All field samples collected at the higher flow rate and the appropriate number of QA/QC samples will be submitted for analysis each week in order to determine if the samples being collected can be analyzed by the ISO TEM method to the required analytical sensitivity. The on-Site laboratory will complete a preliminary analysis of 10 grid openings for each sample to ensure its readability by TEM. Completion of the sample analysis will be performed by an off-Site laboratory. The on-Site laboratory will ship the samples under proper COC to a laboratory designated by the Libby Project laboratory coordinator.

Comment [GH65]: I DISAGREE! Those samples were not representative, used differing methods, evolved over time, had higher DLs, and had less QA/QC than this SAP, so the prior use of 0.8 due to the other air samples being collected, is NOT a reason to use them – only if (and likely not) all other things are equal. Let the objective test comparison data speak for deciding pore sizes.

Sample Archival
All samples not planned for immediate analysis will be archived at a project laboratory as specified by the project laboratory coordinator and sent for analysis only if directed by EPA.

All samples planned for immediate analysis will be distributed to project laboratories as directed by the Libby Project laboratory coordinator. Once analyzed, all samples will be will stored (archived) at project laboratories under COC until further notice.

5.2 Analytical Sensitivity

The target analytical sensitivity for outdoor ambient air for this investigation is 0.00004 s/cc. In the event of sample loading or other issues where a sensitivity of 0.00004 s/cc can not be achieved, the laboratory may report a sample result with a higher (poorer) sensitivity *only after consultation with EPA project personnel.*

Comment [GH66]: Structu res have still not been defined, or at least I have not found them defined anywhere yet. Please do so everywhere.

Comment [GH67]: How does the pore size or loading affect the target DL? Do you know? If not, can you find out? Will you find out and report the results?

5.3 Holding Times

No preservation requirements or holding times are established for air samples collected for asbestos analysis.

5.4 Laboratory Custody Procedures and Documentation

Laboratory custody procedures are provided in the laboratory's QA management plan, which are approved by CDM as part of the laboratory procurement process. Upon receipt at the laboratory, each sample shipment will be inspected to assess the condition of the shipping container and the individual samples. This inspection will include verifying sample integrity. The enclosed COC records will be cross-referenced with all of the samples in the shipment. The laboratory custodian will sign these records and provide copies for placement in the project files. The sample custodian may continue the COC record process by assigning a unique laboratory number to each sample on receipt. This number, if assigned, will identify the sample though all further handling at the laboratory. It is the laboratory's responsibility to maintain internal logbooks and records throughout sample preparation, analysis, and data reporting.

5.5 Documentation and Records

Data reports will be submitted to the CDM laboratory coordinator and include a case narrative that briefly describes the number of samples, the analyses, and any analytical difficulties or QA/QC issues associated with the submitted samples. The data report will also include signed COC forms, analytical data summary report pages, and a summary of QC sample results and raw data, where applicable. Raw data are to consist of instrument preparation and calibration logs, instrument printouts of field sample results, QC sample results, calibration and maintenance records, COC check in and tracking, raw data count sheets, spectra, micrographic photos, and diffraction patterns. All original data reports will be filed in the CDM

Comment [GH68]: How and when will EPA scientists and managers be informed? Please specify if they will get draft reports to review and edit or if they will only get final reports.

project repository in Denver, Colorado. The laboratory also will provide an electronic copy of the data to the laboratory coordinator and others as directed by CDM.

5.6 Data Management

Sample results data will be delivered to the Volpe Center and CDM's Cambridge office both in hard copy and as an electronic data deliverable (EDD). Electronic copies of all project deliverables, including graphics, will be filed by project number. Electronic files will be routinely backed up and archived.

All results, field data sheet information, and survey forms will be maintained in the Libby project database managed by the Volpe Center.

Comment [GH69]: Can the LATAG gain limited access to the data files for all studies, perhaps for the TA and other LATAG members as needed? How? When – after QA and internal reviews have issued final results?

Section 6
Assessment and Oversight

Assessments and oversight reports to management are necessary to ensure that procedures are followed as required and that deviations from procedures are documented. These reports also serve to keep management current on field activities. Assessment, oversight reports, and response actions are discussed below.

6.1 Assessments

Performance assessments are quantitative checks on the quality of a measurement system and are appropriate to analytical work. Performance assessments for the laboratories may be accomplished by submitting reference material as blind reference (or performance evaluation) samples. These assessment samples are samples with known concentrations that are submitted to the laboratories without informing the laboratories that they are performance samples. Samples will be provided to the laboratories for performance assessment upon request from the EPA remedial project manager (RPM) or Volpe Center PM. Laboratory audits may be conducted upon request from the EPA RPM or Volpe Center PM.

Comment [GH70]: Again, PE samples are not defined; are they related to LA asbestos, or to tremolite, and are small particles included? Please expound.

Performance samples will be submitted to each laboratory analyzing samples associated with this investigation. The submission frequency will be at least once every three months.

System assessments are qualitative reviews of different aspects of project work to check on the use of appropriate QC measures and the functioning of the QA system. Project assessments will be performed under the direction of the QA managers, who report directly to the CDM president. Quality Procedure 6.2, as defined in the CDM QA Manual (CDM 2005a), defines CDM 's corporate assessments, procedures, and requirements. Due to the amount of sampling and the duration of the Libby project, both a field audit and an office audit are scheduled for the Site annually.

6. 2 Response Actions

Response actions will be implemented on a case-by-case basis to correct quality problems. Minor response actions taken in the field to immediately correct a quality problem will be documented in the applicable field logbook and a verbal report will be provided to the CDM PM. For verbal reports, the CDM PM will complete a communication log to document the response actions were relayed to him/her. Major response actions taken in the field will be approved by the CDM PM, the EPA RPM, and Volpe PM prior to implementation of the change. Major response actions are those that may affect the quality or objective of the investigation. Quality problems that cannot be corrected quickly through routine procedures may require implementation of a corrective action request (CAR) form.

All formal response actions will be submitted to either CDM 's QA manager and/or project QA coordinator for review and issuance. CDM 's PM or local QA coordinator will notify the QA manager when quality problems arise that may require a formal response action. CAR forms will be completed according to Quality Procedure 8.1 of

the CDM QA Manual (CDM 2005a).

In addition, when modifications to this specific SAP are required either for field or laboratory activities Libby Asbestos Project Record of Modification Form (Appendix C) must be completed.

6.3 Reports to Management

QA reports will be provided to management whenever quality problems are encountered. Field staff will note any quality problems on field data sheets, or in field logbooks. CDM 's PM will inform the project QA coordinator upon encountering quality issues that cannot be immediately corrected. Weekly reports and change request forms are not required for this work assignment. Monthly QA reports will be submitted to CDM 's QA manager by the project QA coordinator.

Topics to be summarized regularly may include but not be limited to:

- Document technical and QA reviews that have been conducted
- Activities and general program status
- Project meetings
- Corrective action activities
- Any unresolved problem
- Any significant QA/QC problems not included above

Comment [GH71]: How and when does EPA staff get into this loop? Don't they get equal chances to review and comment as the sponsors and users? They should. Please explain EPA's interaction.

Section 7
Data Validation and Usability

Laboratory results will be reviewed for compliance with project objectives. Data validation and evaluation are discussed in Sections 7.1 and 7.2, respectively.

7.1 Data Review, Validation, and Verification Requirements

No formal data validation for these media is currently required of CDM. At the request of Volpe Center, CDM will validate data submitted by analytical laboratories. Data validation consists of examining the sample data package(s) against pre-determined standardized requirements. The validator may examine, as appropriate, the reported results, QC summaries, case narratives, COC information, raw data, initial and continuing instrument calibration, and other reported information to determine the accuracy and completeness of the data package. During this process, the validator will verify that the analytical methodologies were followed and QC requirements were met. The validator may recalculate selected analytical results to verify the accuracy of the reported information. Analytical results will then be qualified as necessary.

Comment [GH72]: While validation is stated as not being required, will verifications of results (as described in the SAP) be performed, and at what rate?

Data verification includes checking that results have been transferred correctly from laboratory data printouts to the laboratory report and to the EDD. Data verification for this project is primarily performed as a function of built-in quality control checks in the Libby project database when data is uploaded. However, the sample coordinator will notify the laboratories and the project database manager (Mr. Mark Raney, Volpe Center) of any discrepancies found during data usage.

Comment [GH73]: See above comment.

7.2 Reconciliation with Data Quality Objectives

Once data has been generated, CDM evaluates data to determine if DQOs were achieved. This achievement will be discussed in the measurement report, including the data and any deviations to this SAP. Sample data will be maintained in a Microsoft Access database. Laboratory QC sample data will be stored in hard copy (in the project files) and in a separate database.

Section 8
References

CDM. 2003a. Draft Final Response Action Work Plan.

_____. 2003b. Modifications to Laboratory Activities. Revised December 23, 2003.

_____. 2005a. Quality Assurance Manual. July 7.

_____. 2005b. Technical Standard Operating Procedures Manual. Revision 18. May 6.

_____. 2005c. Analytical Guidance Documents, Volume 1. December.

EPA. 1992a. Supplemental Guidance to RAGS: Calculating the Concentration Term. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. Publication 9285.7-081.

_____. 1992b. Quality Assurance/Quality Control Samples. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. April.

_____. 2001. EPA Requirements for Quality Assurance Project Plans, QA/R-5. Final. March.

_____. 2006a. Guidance on Systematic Planning Using the Data Quality Objective Process, QA/G-4. February.

_____. 2006b. Document submission: letter & report. Transmission & document clarification letter from Bill Murray (dated: June 23, 2006). Summary of Asbestos Levels in Ambient Air in Libby, Montana. Draft Internal USEPA Region 8 Working Document. (Report dated: December 5, 2005)

_____. 2006c. Conceptual Site Model for Ambient Air Exposure Pathways at OU4 in Libby. Draft USEPA Region 8 Working Document, dated:

_____. 2006d. Integrated Risk Information System (IRIS). On-line database of toxicity information created and maintained by USEPA. Available at http://www.epa.gov/iriswebp/iris/index.html .

Haas CN, Rose JB, Gerba CP. 1999. Quantitative Microbial Risk Assessment. John Wiley and Sons, New York.

International Organization for Standardization. 1995. Ambient Air - Determination of Asbestos Fibers - Direct transfer Transmission Electron Microscopy Method. ISO 10312:1995(E).

~~IRIS. 2006. Integrated Risk Information System (IRIS). On-line database of toxicity information created and maintained by USEPA. Available at http://www.epa.gov/iriswebp/iris/index.html.~~

Midwest Research Institute. 1982. Collection, analysis, and characterization of vermiculite samples for fiber content and asbestos contamination. Final report. Washington, DC; U.S. Environmental Protection Agency. Contract No. 68-01-5915.

Page 6: [1] Comment [GH51]	Gerry	9/18/2006 3:40:00 AM

The number of total annual samples per station seems more than necessary at 36 each or 9 per quarter (3 per month, 5 days each); I would suspect that similar results and conclusions should be able to be determined with 24 samples per year per station. Why this number? It seems adequate but may be excessive, since related text claimed 50-100 per subunit may be adequate to discern different spatial patterns. Are you trying to attain that number of 50-100 samples each quarter and for each subunit of 3-5 locations? Please explain

Tony Ward
<tony.ward@umontana.edu>
09/15/2006 03:37 PM

To Bonita Lavelle/EPR/R8/USEPA/US@EPA
cc
bcc
Subject Libby SAP for Ambient Asbestos Monitoring

Hi Bonnie,

I read through the plan, and overall it looks very good, and quite comprehensive. I think it is a solid plan that will address many of the current questions regarding ambient Libby amphibole.

I had a couple of comments/questions:

Page 4-5: Maybe you could list what parameters of meteorological data you will be looking at (i.e. wind speed, wind direction, etc).

Page 4-5: Do you want to list the new Grace met station as a source of met data?

Page 4-6: Is it necessary to have a second sample collected with a lower flow rate (1.5 LPM)? This seems like it would be cost prohibitive. Also, seems that the previous ambient sampling conducted by EPA in Libby can determine if the 2LPM flow rate overloads the filters. Maybe this could be done for the first couple of sample runs, with the both sets of samples analyzed to reestablish the answer to this question.

Page 4-9: It is probably in the report somewhere, but I didn't see anything about continuing to verify the sampler flow rates (continuing calibrations), or conducting flow audits. I'd recommended language about occasional sampler flow verifications, establishing criteria for recalibrating the sampler, and quarterly audits of each sampler.

That's all I have. Thanks for asking me to review the plan. Call me if you have any questions.

Tony J. Ward, Ph.D.
The University of Montana
Center for Environmental Health Sciences
(406) 243-4092

September 14, 2006

Bonnie Lavelle
Remedial Project Manager
EPA Region 8, Denver
Transmittal via e-mail

Re: Draft Sampling and Analysis Plan for Outdoor Ambient Air Monitoring at the Libby Asbestos Site, Libby, Montana (September 5, 2006) (Ambient Air SAP)

Dear Bonnie:

Thank you for providing the Montana Department of Environmental Quality (DEQ) the opportunity to comment on the above referenced document. Following are DEQ's comments.

Section 1.2, Project Schedule and Deliverables: Please consider revising the text to read: "...of data collected is sufficient, *with a minimum of 12 months of data*, to support...." Also, please consider clarifying if the interim data reports will be available to the public and if so at what intervals.

Section 2.1, Site Location, second sentence: The Site description provided depicts the Operable Unit 04 and not the entire Site.

Section 2.2, Site History, fourth bullet: Please consider revising the text to read: "...schools and parks *in and around the City of Libby*." Also, please consider a description of the boundaries of the highway corridors.

Section 2.2, Site History, last paragraph: The text references the site-wide Conceptual Site Model and describes five of the "contaminated media" pathways identified in the July 2006 version of the CSM. It may be helpful to provide a figure of the CSM and highlight the individual pathways investigated through this Ambient Air SAP. This may help the general public put some of the pieces together for the larger Remedial Investigation.

Section 2.3, Summary of Outdoor Ambient Air Monitoring in Libby, third paragraph: The text indicates pre clean-up samples were collected to help determine if the clean-up activities caused a measurable release. Were during and post clean-up samples collected to determine the impact or what were the pre clean-up samples compared to? Please provide further clarification of these sampling activities. (I reviewed the Summary report, EPA 2006b, and the same comment is applicable to that report as well.)

Section 3.4, Step 4, Temporal Bounds, last sentence: Please consider revising the text to read: "...once the data collected from the initial year are ~~collected~~ *evaluated*, and...."

Section 3.7, Step 7, Estimating the Number of Samples Required, third paragraph: Please consistently use either the symbol or the name "sigma" or define the sigma symbol.

Section 4.1.1, Field Planning Meeting, second set of bullet items, last item: Please consider revising the text to read: "Obtain *and maintain* personal protective equipment (PPE)."

Section 4.2.1, Field Logbooks and Records, first paragraph, third sentence: Please consider revising the text to read: "...manage the logbooks ~~and FSDS~~ and will send original...." The FSDS details are found in the next paragraph.

Section 4.2.2, Photographic Documentation: Please consider including the sampling location photograph with subsequent sampling event documents. This may provide a basis for the field teams to document any changes to the integrity of the sampling equipment and the consistency of the original location. (For example, if the equipment is moved, damaged, or the surroundings change, etc.)

Section 4.3.2.2, Sampling Schedule: Table 4-1 does not illustrate the Helena sample having the same sample schedule as those in Libby as described in the text. Nor does Table 4-1 reflect the Eureka schedule as described in the text. Please revise either the text or the table to accurately reflect the intended schedules.

Section 4.3.2.3, Filter Type: Please consider providing additional justification for the pore size other than because that is what was used in the past. Please include an explanation of what a "meaningful difference" may be; what kind of changes may be necessary; and how such changes would be implemented.

Section 4.3.2.4, Sample Height, second paragraph, first sentence: Please consider revising the text to read: "...whether levels may ~~tend to be higher~~ *be different* at a child's...."

Section 5.1, Analytical Methods, third paragraph: Please consider revising the text to acknowledge the potential for change based on the paired sample results described in Section 4.3.2.3.

Section 5.4, Laboratory Custody Procedures and Documentation, second to last sentence: Please revise the text to read: "...identify the sample ~~though~~ *through* all further...."

Section 6.2, Response Actions, third paragraph: Please revise the text to read: "...or laboratory activities, *a* Libby Asbestos Project...."

Please feel free to contact me with any questions or concerns. I can be reached at 406-841-5040 or electronically at clecours@state.mt.us.

Sincerely,

Catherine LeCours
Superfund Project Manager
Remediation Division